ELSEVIER

International Journal of Medical Informatics 47 (1997) 193–214

International Journal of Medical Informatics

SUTIL: Intelligent ischemia monitoring system

J. Vila [a], J. Presedo [a], M. Delgado [a], S. Barro [a,*], R. Ruiz [b], F. Palacios [c]

[a] *Departamento Electronica y Computacion, Facultad de Fisica, University of Santiago de Compostela, 15706, Santiago de Compostela, Spain*

[b] *University of Murcia, Cartagena, Spain*

[c] *General Hospital of Elche, Elche, Spain*

Received 3 July 1996; accepted 3 November 1997

Abstract

SUTIL is an intelligent monitoring system for intensive and exhaustive follow up of patients in coronary care units. This system processes electrocardiographic and hemodynamic signals in real time, with the main objective of detecting ischemic episodes. In this paper, we describe the tasks included in SUTIL. In addition to basic tasks, those at higher levels will also be presented. Some of these latter tasks attempt to mimic, to some extent, the way in which the human expert operates. © 1997 Elsevier Science Ireland Ltd.

Keywords: Ischemia detection; CCU patient monitoring; Signal processing; Intelligent monitoring; Real time

1. Introduction

The development of the health sciences and of information technology has resulted in a large increase of the number of signals and the amount of data and information that is currently evaluated in coronary care units (CCUs). As a result, the monitoring and the follow up of patients in these units has become extremely complex.

Acute myocardial infarct (AMI) is frequently seen in CCU patients. AMI, or ischemic necrosis of the left ventricle, is the final result of the irreversible reduction of the blood flow and hence, the provision of oxygen to the heart muscle. When an infarct occurs the myocardial muscle evolves towards a situation of permanent instability. In this process, it goes through an ischemic phase in which the muscular mass affected can still be recovered as viable tissue.

One of the objectives of CCUs is to prevent an ischemic episode from evolving into

* Corresponding author. Tel.: + 34 81 563100; fax: + 34 81 599412; e-mail: elsenen@usc.es

PII S1386-5056(97)00095-6

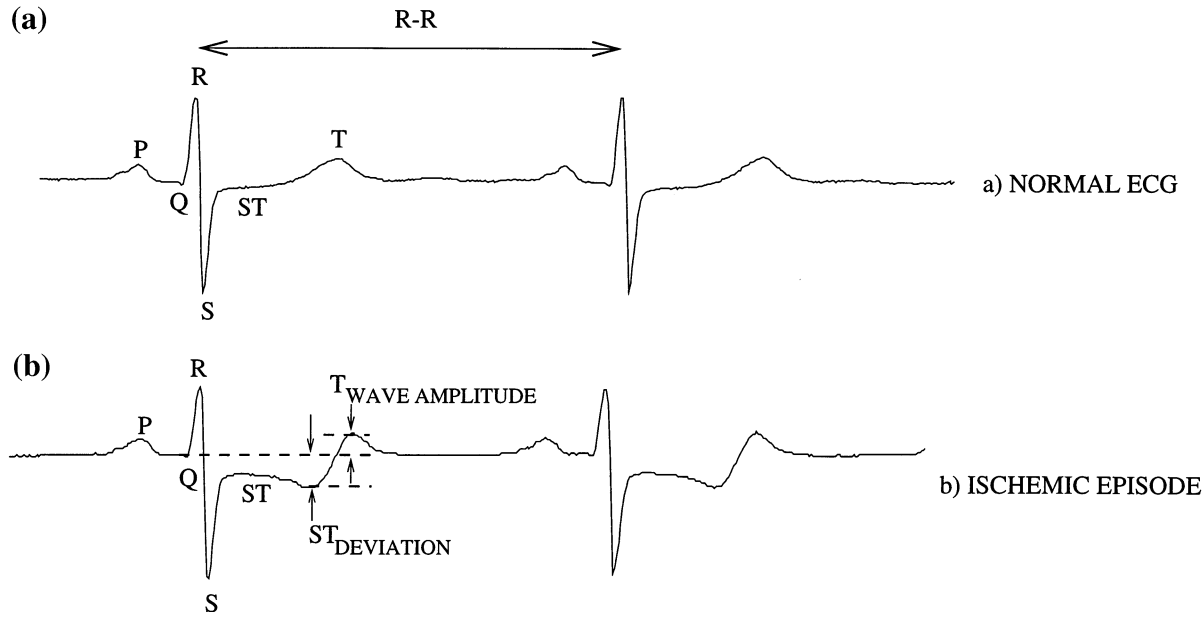

Fig. 1. (a) ECG signal for a normal patient; and (b) during an ischemic episode.

an irreversible necrosis situation (AMI). Physicians usually employ surface electrocardiographic signals (ECG) as a monitoring signal, as it is a non invasive signal that is relatively easy to obtain and which, in general, displays notable changes when an ischemic episode occurs. The effects of an ischemic crisis appear as modifications in the morphology of the ST segment, the T wave or in both areas (Fig. 1). However, it is not always possible to detect an ischemic episode purely through the analysis of the ECG, as the difference between a normal and an abnormal ECG may be difficult to discern, even for specialists [1]. To model and handle this imprecision in medical knowledge we have chosen an approach based on fuzzy set theory.

In general, current real time patient monitoring systems carry out very poor processing of the ECG signal. In most cases they merely extract a small number of significant variables and display them in the form of trend plots. At most, they establish alarms based on the application of simple threshold criteria [2–4].

Taking these considerations into account, we have decided to develop an intelligent monitoring system (SUTIL), aimed at monitoring patients with ischemic cardiopathies that are confined to CCUs. This monitoring system processes three electrocardiographic leads and one invasive cardiovascular pressure signal in real time and its main objective is the detection of ischemic episodes in the patient being monitored [5].

2. Hardware description

The current architecture of SUTIL consists of two subsystems. The first—the signal processing subsystem—is aimed at low and medium level signal processing tasks, whereas the second—the user interaction subsystem—basically performs user-system interac-

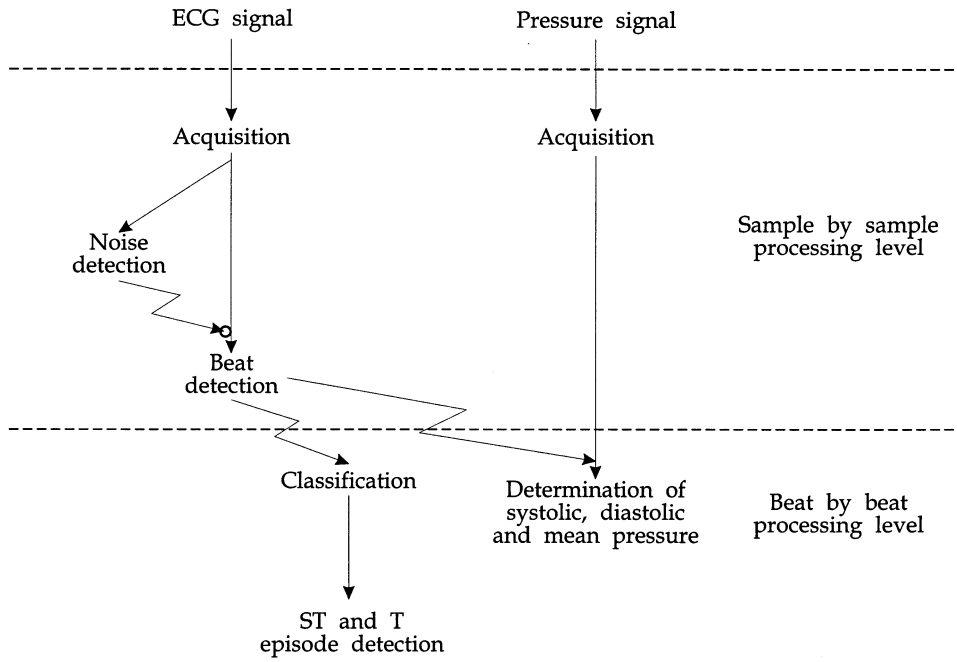

Fig. 2. Structure of SUTIL at the processing block level (the dashed arrows indicate situations where new routines are triggered, ⇝; or disabled, –◦).

tion processes, massive information storage and medium and high level processing. The signal processing subsystem consists of a 12-bit A/D converter and a 32 bit 25 MHz 68030 processor with a 68882 co-processor, 4 Megabytes of RAM and an ethernet interface. These components are connected through a VME bus [6]. The system runs the OS-9 real time operating system.

The user interaction subsystem is a SUN SparcStation 10 under UNIX, equipped with 32 Megabytes of RAM memory, a 1.05 Gigabyte hard disk, a massive storage tape drive (hexabyte 8500) and a CDROM unit.

3. Software description

Our system can be broken down into tasks, among which there is a hierarchy imposed by the frequency and the mode (synchronous or asynchronous) in which they are executed. From this point of view, we can classify the tasks of the signal processing subsystem into one of the following categories (Fig. 2): sample-by-sample and beat-by-beat.

3.1. Sample by sample

In this category we find all those tasks that are executed with each new sample acquired. They are tasks whose execution is clearly synchronous, as they are executed at precise instants of time. Within this category the main tasks are:

Acquisition. This task reads the data acquisition driver and stores the sampled signals in cyclic buffers. The three ECG leads are sampled at a frequency of 500 Hz, as recommended by the American Heart Association [7]. Pressure signals are sampled at a rate of 250 Hz.

Noise detection. We have opted for a design of algorithms to detect different classes of noise (high frequency noise and noise due to the saturation of the electrocardiographer and/or the analogue to digital converters). The signal intervals with a high level of contamination are not used in further analysis steps.

Beat detection. The performance of an ECG processing system depends, to a great extent, on the reliability of the detection of the cardiac cycles. The detection of a cardiac cycle in most monitoring systems (including this one) is carried out through the detection of the QRS complex. We have chosen a classical scheme based on a linear filtering of the signal and the application of an adaptive threshold [8]. The purpose of the filter is to enhance QRS complexes in the signal and at the same time attenuate the rest of the electrocardiographic signals. The position of maxima of the filtered signal that exceed the adaptive threshold indicate the fiducial marks in the QRS-complexes. The threshold value will depend on the maxima detected in previous beats.

Although our QRS detector operates only on one channel it always selects that which a priori displays the best characteristics, i.e. the one that is free of noise and with a higher value for the detection threshold.

3.2. Beat by beat

In this category we find all those tasks that are executed for every newly detected beat. They are obviously asynchronous tasks, as a beat event may occur in any instant of time. Within this category we could place the following tasks:

Delineation of the QRS complex. For an in depth analysis of the characteristics of a beat, it is not enough to have a stable fiducial mark. There is a large scope of measurements which can be performed over a beat and which depend on the result of the process of delineating the QRS complex. In addition, in many instances it is clinically relevant to measure the width of the complex.

The algorithm employed for the delineation of QRS complexes uses a Hanning filter, which as a result provides a pulse, the width of which is similar to the width of the QRS from which it comes. Following the recommendations of CSE for multilead analysis [9] the real onset of the QRS is the earliest among the three and the real end of the QRS (J-point) is the latest of the three.

Detection of the isoelectric level. The CSE [9] recommends that for amplitude measurements in the QRS complex, the ST segment or T wave be taken relative to an isoelectric level determined from the values of the signal just before the onset of the QRS complex. In this line, the algorithm we have implemented basically consists in seeking an area that is more or less flat before the beginning of the QRS complex, as determined by the previous task.

Delineation of the waves that make up the QRS complex. The height and width of each of the waves that make up the QRS complex are relevant parameters for monitoring. To extract this information we have again taken into account the recommendations provided by the CSE [9,10]. Our implementation of these criteria is based on a grammar [11] that specifies the structurally correct configurations characterising QRS complexes. The set of terminal or primitive elements of this grammar is made up of:

1. Waves. These may be positive or negative. They are segments of the signal comprised between two consecutive crossings of the isoelectric line and which satisfy the minimum requirements of the CSE regarding amplitude (20 μV) and duration (6 ms).

2. Segments. They are segments of the ECG signal found between two consecutive crossings of the isoelectric and which do not satisfy all of the minimum requirements of the CSE for considering the segment as a wave.
3. Final segment. This is a segment of the signal between the end of the last wave of the complex and the point associated with the end of the QRS complex.

In this model it is possible to define a set of rewriting rules which enables us to assign to each QRS complex a word belonging to an alphabet (in our case, the set of possible labels that a QRS complex can be assigned as a function of the waves present) from its previous segmentation into its constituting primitives.

Morphological classification. Once the QRS complexes have been correctly detected, it is necessary to perform their classification in order to successfully complete the rhythm identification process.

Any ischemic process has effects on the ECG, in particular on the ST segment and/or the T wave of the cardiac complexes whose origin is the sinoauricular node (normal beats). Therefore, a correct characterisation of the QRS complexes into two large groups—normal and aberrant complexes—is necessary. For the beats that are classified as normal, characteristics are determined which permit a decision as to whether or not an ischemic process is taking place.

The discrimination of normal beats has mainly been based on their morphological and rhythmic normality. Morphological normality is established through a process of comparing raw ECG signal, corresponding to QRS complex of each new beat detected to an adaptive template which evolves according to those normal QRS complexes which have been previously identified. We have chosen this technique due to the fact that it does not require too much computational power.

For each beat classified as normal by the morphological classification process, we extract a set of features that will be used in a later process for the detection of ischemic episodes. Among the features we extract are (Fig. 3):

1. ST segment amplitude. In general, measurements extracted from the ST segment are used for the detection and quantification of the severity of ischemic episodes in patients with ischemic cardiopathies. One of the most frequently used measurements is the deviation of the ST segment at one or more points with respect to the isoelectric level. The most widely used measurement is that at 80 ms after the end of the QRS complex. However, at high rates this point may be in the T wave rather than in the ST-segment. Therefore, we followed the recommendations of the European ST–T Database (ESC DB) [12], to use the amplitude of the $J+80$ ms point when the heart rate is below 120 beats per minute and the $J+60$ ms point is otherwise.
2. Slope of the ST segment. A significant deviation of the ST segment is usually related to the existence of an ischemic episode. Nevertheless, this is not always the case and many cardiologists also take the value of the slope of the ST segment into account. As the

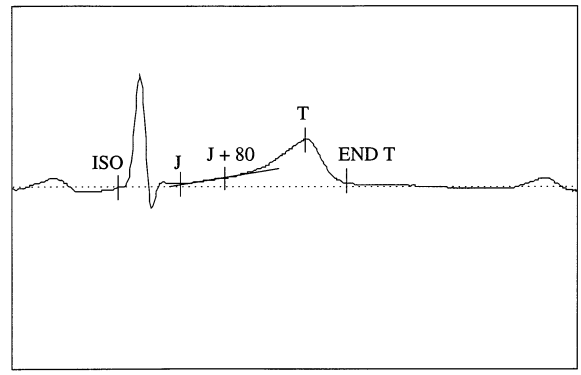

Fig. 3. Parameters extracted from each normal beat for the detection of ischemic episodes.

relationship between the changes in the slope of the ST segment with ischemic episodes is not well established, we have decided to measure this slope, but we do not make an evaluation of ischemic episodes based on its values for the time being.

3. Amplitude of the T wave. The most important characteristic of the T wave is its amplitude. This measurement is performed with respect to the isoelectric level, according to the recommendations of the CSE. The amplitude of the T wave is defined as the maximum deviation with respect to the isoelectric of the ECG signal between the beginning and end of the T wave.

We consider the onset of the T wave to be the point at which the deviation of the ST segment has been measured, i.e., J + 80 or J + 60 ms. Rather than designing an algorithm that finds the end of the T wave, we use one of the formulae for predicting the duration of the QT interval as a function of the average heart rate, as presented by Rautaharju et al. [13]

$$QT = 1/(a + b \times HR) \quad (1)$$

HR being the heart rate in beats/minute and QT the interval between Q and T waves in milliseconds. Parameters a and b have different values depending on the sex of the patient: $a = 1.64 \times 10^{-3}$ and $b = 1.41 \times 10^{-5}$ for men and $a = 1.50 \times 10^{-3}$ and $b = 1.54 \times 10^{-5}$ for women.

In order to monitor the change in the morphology of normal beats, our system periodically constructs templates that are the result of averaging original normal beats. These templates have a noise level that is much lower than the ECG signal and may be used to detect details that would be hidden in the original signal. However, it is not possible to employ these templates in the monitoring of ischemic episodes (extracting the necessary parameters from them instead of doing it directly from the ECG signal) due to the low temporal resolution obtained when a significant reduction of the noise is desired.

3.3. Detection of ischemic episodes

In this section, we will describe the set of tasks executed in SUTIL in order to detect episodes related to ST and T changes [5]. The tasks related with the detection of ischemic episodes are activated each time the deviation of the ST segment and the amplitude of the T wave are evaluated. Once these parameters have been obtained, an interpolation is performed to obtain an equally spaced time series with an equivalent sampling frequency of 1 Hz. Over this set of data, a set of tasks is executed (Fig. 4) in order to identify the beginning and end of each ischemic episode, as well as the degree of confidence we have in the detection being correct. A more detailed description of these tasks, as well as other related tasks that may be required, can be found in [14,15]. Here we will pay more attention to the description of the way in which they have been implemented in our monitoring system.

3.3.1. Definition of the concept of ST and T episodes

In general, it is not possible to reliably decide on the presence or absence of an ischemic period from the ECG alone. It is generally assumed that changes in the ST segment and the T wave are related with the presence of these episodes, although other causes, such as movements of the patient, may also provoke these changes. Therefore, it is necessary to have a standard that permits the evaluation of the algorithms developed for the detection of ischemic episodes from the ECG signal alone.

The ESC DB [12] has been established for evaluating ECG analysis systems whose ob-

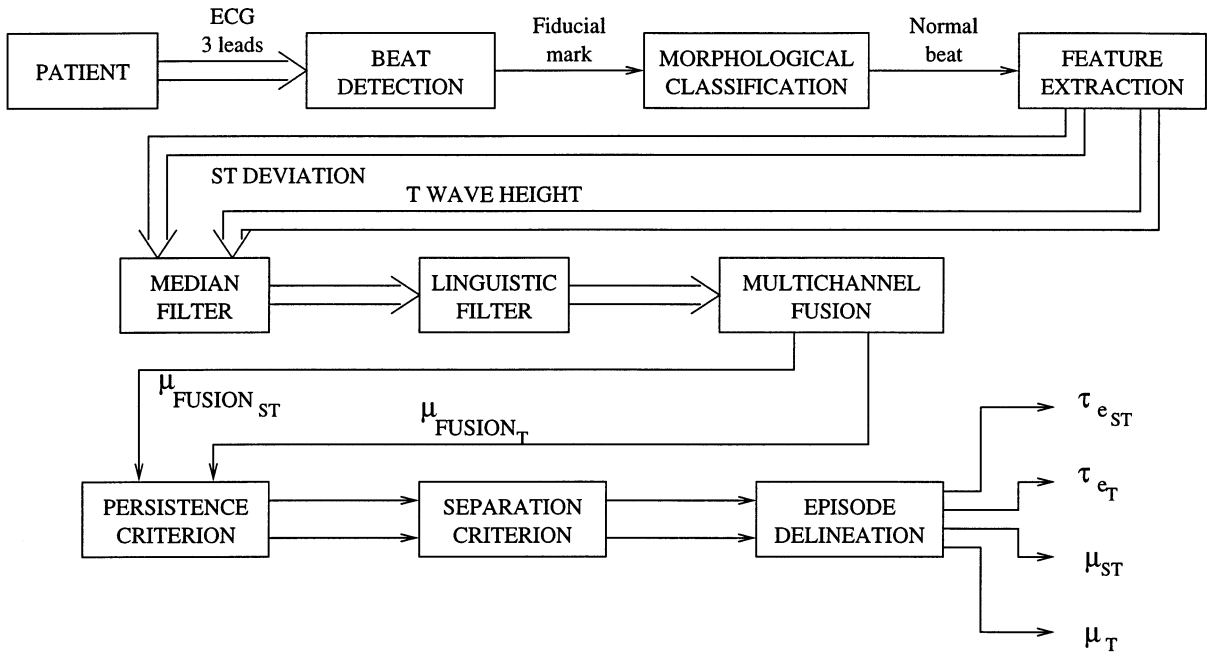

Fig. 4. Stages of the ischemic episode detection process.

jective is the detection of ischemic episodes. This database contains 90 ECG recordings, each one 2 h long, which have been manually annotated by a group of expert cardiologists.

As has previously been mentioned, there is no universally accepted criterion for defining ischemia using parameters from the ECG signal alone. Instead of attempting to annotate all the ischemic episodes in these ECGs, it was decided to annotate only those signal events which were sufficiently significant to be considered as ischemic episodes.

The following significant events are defined (presumably related with ischemic episodes):

ST episode. For an episode to be considered as an ST episode, the following conditions must be met:

1. The absolute value of the ST segment amplitude change relative to the reference value in baseline conditions must be more than 1 mm (0.1 mV).
2. This change must be maintained for at least 30 s.
3. For two episodes to be considered different, the distance between them must be at least 30 s.

T episode. The definition of a T episode is completely analogous to that of an ST episode, except for the fact that a threshold of 0.2 mV is chosen. The absence of definitive criteria leads us to use these criteria for the detection of ischemic episodes with some reservations. A less strict application of the criteria may, in our view, have a positive effect on the detection of ischemic episodes. We chose to fuzzify the thresholds in the above definitions and to develop a fuzzy detection of ischemic episodes. Our fuzzy detection algorithm is based on fuzzy set theory, introduced by Zadeh [16].

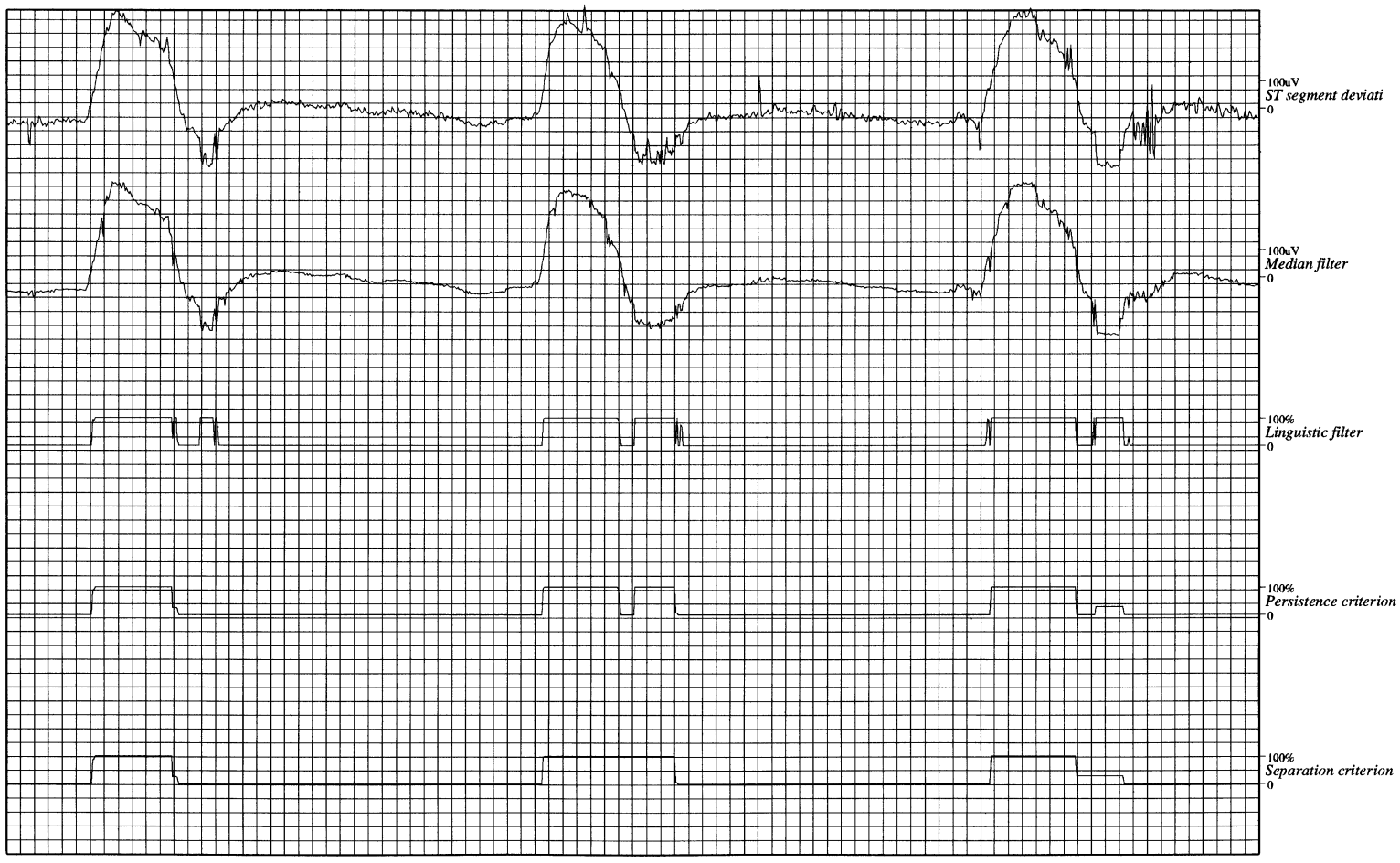

Fig. 5. Example of the transformation of the trend diagram of an ST segment amplitude by the application of the sucessive stages of our ischemic episode detection algorithm (five squares are equivalent to 1 min). It can be appreciated that the patient suffers several ST episodes (extracted from recording eO113 of the European ST–T Database).

3.3.2. Median filter

The measurements in the ST segment and the T wave are taken for all normal beats. A large variability in the parameter values is expected due to noisy recordings. To eliminate this noise—which in some cases could lead to false detection of ischemic episodes—we make use of a median filter, similar to the one described in a paper by Heinonen and Neuvo [17]. This reduces the variability in the trend diagrams for the ST deviation and the amplitude of the T wave.

The output of the filter at time t is the central value of the measured parameter values in a 15 s window around time t. In Fig. 5 we show the result of applying this filter to a trend diagram corresponding to the deviation of the ST segment. Typical behaviour of a low pass filter can be observed, eliminating most of the variability present.

3.3.3. Linguistic filter

After eliminating the trend diagram variability of the ST segment deviation and the T wave amplitude, the next step consists of determining those areas in which we find significant deviations from a clinical point of view. We use a linguistic filter to identify these areas.

We consider that any numerical variable V, whose value at instant $t\in\tau$ is $v(t)\in U$, has at least one representative in the domain of the linguistic variables. This linguistic variable L, takes values from a set of linguistic labels $\{l\}$, each of which is identified with a fuzzy subset of U, where $\mu_l(u)\in[0,1]$ represents the degree to which $u\in U$ belongs to this fuzzy subset.

Linguistic filter. Given a temporal sequence of values $S_V=\{v(t_i),\ \ldots,\ v(t_j)\}$ for a variable V, whose temporal definition domain is represented by $\tau_{S_V}=\{t_i,\ \ldots,\ t_j\}$, application of the linguistic filter associated to the linguistic label l is a transformation of this sequence into the sequence $F_l(S_V)=\{\mu_l(v(t_i)),\ \ldots,\ \mu_l(v(t_j))\}$. A linguistic filter is, consequently, an information abstraction mechanism. In this case for example, the linguistic value according to which we want to 'filter' the sequence of values for the deviation of the ST segment and the amplitude of the T wave is high deviation (or significant deviation at the clinical level). We have taken common cardiological criteria to describe the concept of 'high deviation', resulting in the following composition of trapezoidal possibility distributions[1]: for the deviation of the ST segment $\pi_{\mathrm{hd\_ST}}=((-\infty,\ -\infty,\ -0.1,\ -0.05),\ (0.05,\ 0.1,\ \infty,\ \infty))$ in mV (Fig. 6), whereas for the amplitude of the T wave the trapezoidal distribution will be $\pi_{\mathrm{hd\_T}}=((-\infty,\ -\infty,\ -0.2,\ -0.15),\ (0.15,\ 0.2,\ \infty,\ \infty))$ in mV. It should be noted that we are assuming an

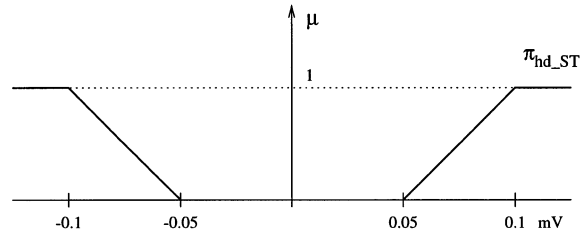

Fig. 6. Possibility distribution representing the semantics of the linguistic value 'high deviation' for the ST segment.

[1] We define a trapezoidal possibility distribution π by four parameters $(a,\ b,\ c,\ d)$ such that $\pi(x)=0$ if $x\le a$ or $x\ge d$, $\pi(x)=1$ if $a\le x\le b$ and having a linear behaviour in the rest: $\pi(x)=(x\text{-}a)/(b\text{-}a)$ if $a\le x\le b$ and $\pi(x)=(x\text{-}d)/(c\text{-}d)$ if $c\le x\le d$.

identity relation between possibility distributions and membership functions ($\pi_l(x) = \mu_l(x)$, $\forall x$).

In Fig. 5 we display, as an example, the result of applying a linguistic filter to a filtered trend diagram of the ST segment deviation.

3.3.4. Multichannel fusion of information

When more than one electrocardiographic lead is monitored and we speak of the duration of an ischemic episode, the temporal extension $\tau = \{t_i, \ldots, t_j\}$ is generally referred to, such that $\forall t \in \tau$, indicating a significant episode in one of the leads.

Consequently, before applying the duration and separation between episodes criteria, a multichannel fusion process is carried out with the information provided by the linguistic filter, with the aim of obtaining for each instant of time the degree of certainty of being in a significant deviation of the ST segment or the T wave in any of the electrocardiographic leads monitored. In our case, the degree of certainty associated with being within an area having significant deviation in the ST segment will be given by:

$$\mu_{\mathrm{FUSION_{ST}}}(t) = \max_i \mu_{\mathrm{hd\_ST}}(\mathrm{ST\ \ Level}_i\ (t)) \tag{2}$$

where hd_ST is the linguistic value associated with the label 'high deviation in the ST segment' and ST $\mathrm{Level}_i(t)$ the value of the deviation of the ST segment in lead i at instant t. Similarly, it is possible to determine the degree of certainty associated with being within an area with significant deviation in the T wave by applying the previous formula to the trend diagram corresponding to the deviation of the T wave.

It must be pointed out that we have distinguished between episodes caused as a consequence of a deviation of the ST segment and those whose cause is a change in the amplitude of the T wave, mainly because the first case is related to the concept of lesion whereas the second one is related more to the concept of ischemia. These two concepts have a different clinical value.

3.3.5. Persistence criterion

Once the possible ischemic episodes have been determined, it is necessary to apply a persistence criterion to guarantee that the episode has a duration of more than, or approximately equal to, 30 s (taking into account that a threshold relaxation process is being carried out). We consider that it is necessary to formally describe some concepts:

Episode. Given a temporal sequence S_V, an episode $e_l \subseteq S_V$ is the longest temporal sub-sequence $e_l = \{v(t_m), \ldots, v(t_n)\}$ for which $\mu_l(v(t_k)) > 0$, $\forall v(t_k) \in e_l$.

Persistence criterion. An episode $e_l = \{v(t_m), \ldots, v(t_n)\}$ constitutes a temporal context in which there is a non-null degree of persistence of the linguistic property of value l. The degree with which $v(t) \in e_l$ is included in a temporal context of duration $m \in \mathbb{I}$ where the linguistic value l persists, is given by the following expression:

$$\forall m \in \mathbb{I}\ \mu_{e_l,m}(t) = \max_{\substack{m = t_q - t_r \\ t_q,\, t_r \in \tau_{e_l}}} \ \min_{t_r \le t \le t_q} \{\mu_l(v(t))\} \tag{3}$$

where τ_{e_l} is the temporal domain where episode e_l is defined.

This equation defines the application of a precise persistence criterion of value m. If the persistence criterion applied was a precise temporal extension (e.g. $m \geq 30$ s), the previous criterion would then be transformed into a condition which would imply determining the maximum of $\mu_{e_l,m} \forall m \in \mathbb{I}$ such that $m \geq 30$ s. However, we are interested in applying a fuzzy time extent [18] (larger or approxi-

mately equal to 30 s) which in this case, corresponds to the distribution $\pi_p = (20, 30, \infty, \infty)$ in seconds.

In a case such as this, where we have a distribution π_p associated with a given value of persistence, the application of the previous criterion is translated into the following expression:

$$\mu_{e_l,p}(t) = \max_{m \in \mathbb{I}} \min\{\mu_p(m), \mu_{e_l,m}(t)\} \quad (4)$$

From this, it is easy to define the concept of an ST or T episode (without taking into account the episode separation criterion). For example, the degree of certainty of being within a temporal context in which we have the persistence required for the linguistic value hd_ST associated with a 'large deviation in the ST segment' situation is given by the following equation:

$$\mu_{st}(t) = \max_{m \in \mathbb{I}} \min\{\mu_p(m), \max_{\substack{m = t_q - t_r \\ t_q,\, t_r \in \tau_{e_{\mathrm{hd\_ST}}}}} \min_{t_r \le t \le t_q} \{\max_i \mu_{\mathrm{hd\_ST}}(\mathrm{ST\ Level}_i(t))\}\} \quad (5)$$

Using the same method, it is possible to determine the degree of certainty of being within a T episode, just by using another linguistic filter, this time over the trend diagram corresponding to the deviation of the T wave, obtaining as a result $\mu_t(t)$.

As an example, in Fig. 5 we present the application of the persistence criterion expressed by the previous equation over a trend diagram corresponding to the deviation of the ST segment of a patient that has experienced several ischemic events.

3.3.6. Separation criterion

The next step in the process of detecting ischemic episodes consists of applying the criterion for the separation between episodes, so that episodes occurring close together are considered as a single episode. For this, the degree of certainty of being outside an ST episode is defined as:

$$\bar{\mu}_{st} = 1 - \mu_{st} \quad (6)$$

where $\tau_{\bar{e}_{st}}$ represents the temporal domain associated with the absence of an ST episode. In the same way, we could define the degree of certainty of being outside a T episode ($\bar{\mu}_t$ being $\tau_{\bar{e}_t}$, its associated temporal domain).

Applying a criterion for the separation between episodes is equivalent to applying a persistence criterion over the condition of absence of an episode. In our case, the fuzzy time extent used is the trapezoidal distribution $\pi_s = (30, 45, \infty, \infty)$ in seconds, so that the non null degree of certainty begins after 30 s, as could be expected from the definition of ischemic episodes given by the ESC DB, becoming equal to one from 45 s onwards. With this we are assuming that when we find two episodes which present a separation that is equal to or greater than 45 s, we are completely certain that they are different. Therefore, from a fuzzy point of view, we could define the concepts of ST and *T* episodes as follows:

Def. *ST episode*. We define ST episode as the longest temporal sequence $e_{\mathrm{ST}} = \{\mathrm{ST\ Level}(t_m), \ldots, \mathrm{ST\ Level}(t_n)\}$ for which we have $\mu_{\mathrm{ST}}(t) > 0$, $\forall t \in \tau_{e_{\mathrm{ST}}}$, where μ_{ST} is given by the following expression:

$$\mu_{\mathrm{ST}}(t) = 1 - \max_{m \in \mathbb{I}} \min\{\mu_s(m), \max_{\substack{m = t_q - t_r \\ t_q,\, t_r \in \tau_{\bar{e}_{st}}}} \min_{t_r \le t \le t_q} \{\bar{\mu}_{st}(t)\}\} \quad (7)$$

Def. *T episode*. We define a T episode as the longest temporal sequence $e_{\mathrm{T}} = \{\mathrm{T\ Level}(t_m),$

…, T Level(t_n)} for which we have $\mu_T(t) > 0$, $\forall t \in \tau_{e_T}$, where μ_T is given by the following expression:

$$\mu_T(t) =$$

$$1 - \max_{m \in \mathbb{I}} \min\{\mu_s(m), \max_{\substack{m = t_q - t_r \\ t_q, t_r \in \tau_{\bar{e}_t}}} \min_{t_r \le t \le t_q} \{\bar{\mu}_t(t)\}\} \tag{8}$$

Once the ST (e_{ST}) and T (e_T) episodes have been temporally bounded, that is, their temporal domain $\tau_{e_{ST}}$ and τ_{e_T} have been defined in a precise manner, we will take as the confidence degree associated with the detection of these episodes the following:

$$\mu_{e_{ST}} = \max_{t \in \tau_{e_{ST}}} \{\mu_{ST}(t)\} \tag{9}$$

$$\mu_{e_T} = \max_{t \in \tau_{e_T}} \{\mu_T(t)\} \tag{10}$$

These values, which convey the global confidence with which the presence of an ST episode or a T episode can be assumed, are important parameters of the process of presenting information to the user of the system.

3.4. User interaction subsystem

The user-system interface in SUTIL is data driven. The data comes from two main sources:

- Data from the signal processing subsystem, received through the ethernet interface.
- Data from the user. Most of these data come from the interaction of the user by means of the mouse, it rarely being necessary to use the keyboard. This facilitates the learning and use of the system. On some occasions the user can request, by use of the keyboard or the mouse, the monitoring conditions to be modified. These requests are transmitted to the VME system.

The graphical interface provides the following output:

- Graphic interaction. This is the most important output of the interface. It is carried out by means of events, according to the X11 protocol, processed by an XWindow server.
- Acoustical interaction for warnings and alarms.
- Information storage in a format compatible with the MIT-BIH database [19].
- Generation of printed reports.
- Control of the signal processing subsystem by means of sending requests through the ethernet network, either initiated by the user, or because of needs imposed by a possible high level processing block which requests this modification.

The structure of the system itself led to the design of a multi-window user-system interface, in which the information is presented to the user in a structured way, so that the user always knows to which window he/she must resort in order to obtain the information he/she requires. In Fig. 7 we present a view of this interface in which some of the most representative windows are open. The signal window (top centre), shows the ECG and cardiovascular pressure signals in real time, moving from right to left. On this window, it is also possible to view the signals at any instant during the last hour. The selection of the interval to be viewed may be carried out by explicitly referencing the time desired, or in an indirect way through the selection of an event of interest detected by the system (a beat, an ischemic episode, etc). Other windows in Fig. 7 are: the basal window (lower right), which permits viewing of the basal beats and the results of the measurements carried out over them; the trend window (lower left part) in which we represent the

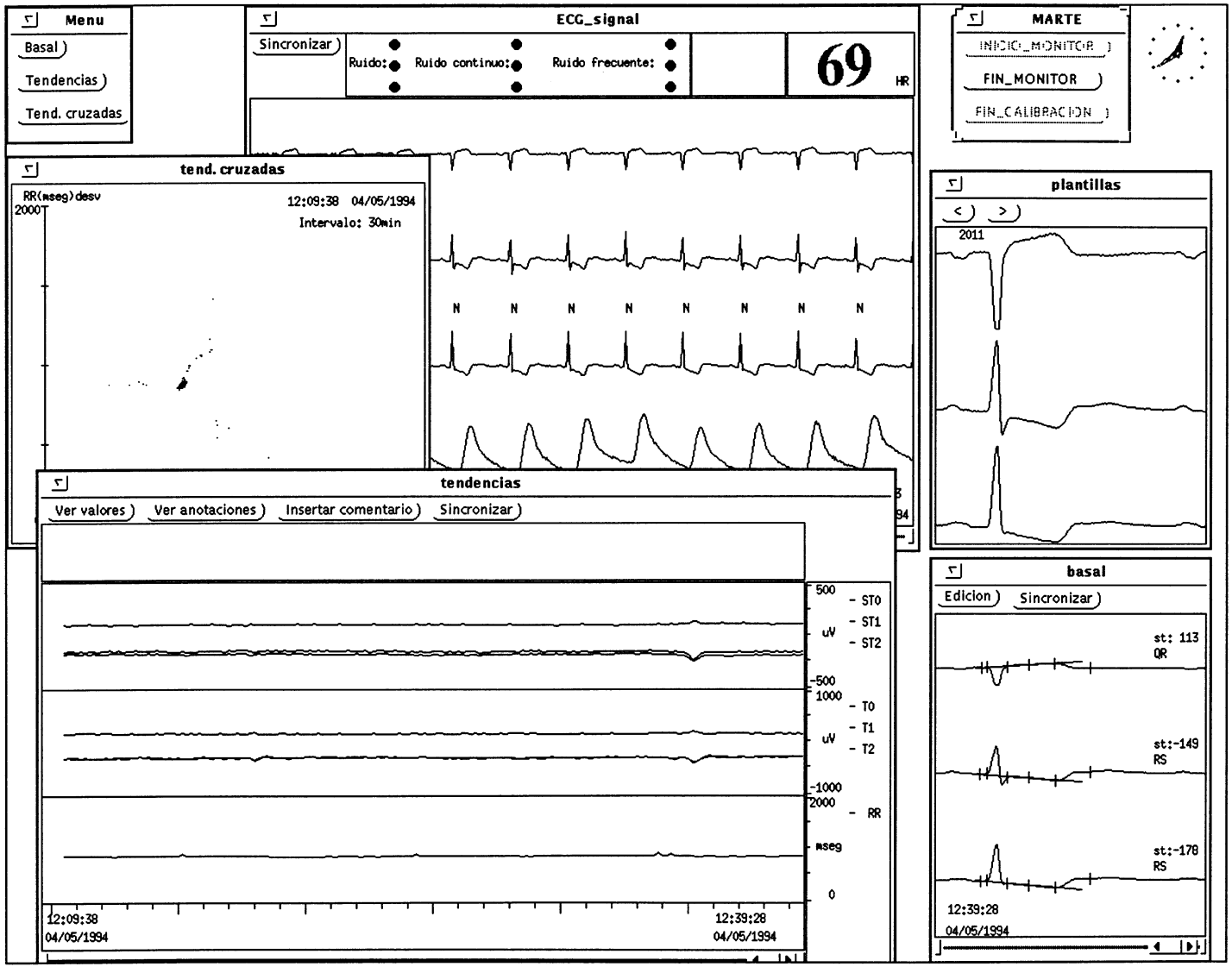

Fig. 7. Illustration of the user–system interface of SUTIL.

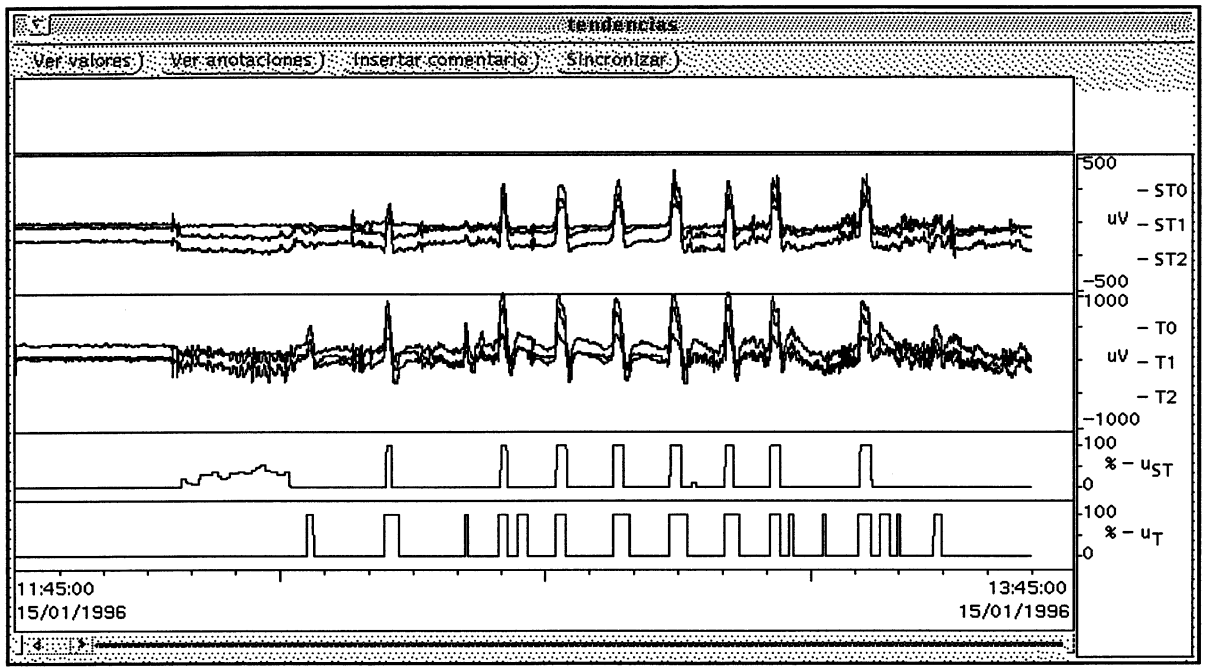

Fig. 8. Illustration of the use of a trend diagram for viewing of the certainty degree associated to the detection of ST and T episodes.

evolution over time of certain parameters (in this example we represent the deviation of the ST segment and the amplitude of the T wave for each of the three ECG leads being monitored, as well as the RR interval); and the crosstrend window (top left) which plots any two parameters in a two dimensional representation.

It is also possible to represent the degree of certainty associated with being within an ST episode ($\mu_{ST}(t)$) or a T episode ($\mu_T(t)$) in the trend window. In Fig. 8 we show the trend diagrams of the deviation of the ST level and the amplitude of the T wave for each one of the channels being monitored, as well as the parameters $\mu_{ST}(t)$ and $\mu_T(t)$.

Each time an ischemic episode is detected (non null certainty degree in $\mu_{ST}(t)$ or $\mu_T(t)$) the system informs the user through an auditive and/or visual alarm. Once the temporal extension of the episode detected has been delimited ($\tau_{e_{ST}}$ or τ_{e_T}), its amplitude and duration are presented to the user, as is the final confidence degree associated with its detection.

4. Validation with data bases

The European ST–T Database [12] was chosen for the validation of our system. In this data base, each recording contains at least one annotation of ischemia, based on the presence of deviations in the ST segment or changes in the T wave. We validated the different algorithms of our system according to the recommendations of the Association for the Advancement of Medical Instrumentation (AAMI) [20]. The QRS complex detector, the morphological classification and the algorithm for the detection of ischemic episodes were validated.

Table 1
Sensitivity and positive predictivity of the QRS complex detection

	QSe	Q+P
Gross	99.32	98.97
Average	99.39	98.98

4.1. Validation of the QRS complex detector

The AAMI recommends validating a QRS detector on the American Heart Association (AHA) database, the Massachusetts Institute of Technology (MIT-BIH) database and the ESC DB. Only the ESC DB database [12] was used, since of the three, this is the only one having information on ischemic episodes.

The validation was carried out over 38 randomly selected recordings of the 90 recordings in the ESC DB. These recordings had a total of 324 278 beats[2], 747 of which were ventricular extrasystoles and 15 of which were the result of the fusion of ventricular and normal beats. From this set, 321 358 normal beats, 697 ventricular beats and 14 fusion beats were correctly detected. In addition, we found a total of 3367 false positive detections and 2158 normal beats; 50 ventricular beats and a fusion beat were not detected. This shows a good performance, with sensitivity and positive predictivity of approximately 99%. In Table 1 we summarise the data obtained from this validation. The AAMI recommends that, in general, when sensitivity and positive predictivity measurements are presented, these be calculated using two different methods. The gross statistics are sensitivity and positive predictivity values, determined over all the ECGs analysed as if they were from one single registration, whereas the average statistics are the averages of the sensitivities and positive predictivities as found in the recordings analysed.

[2] Number of beats that were estimated as being sufficient for validation purposes.

4.2. Validation of the QRS complex morphological classifier

The morphological classifier divides the beats detected into two possible categories: normal beats and all the rest. In our case they have been labelled as non classifiable. In Table 2 we display the results of recordings of the ESC DB, with the largest number of ventricular beats. As can be seen, the number of ventricular beats which are incorrectly classified is relatively low. This is not so in the opposite case, as, for example, in register e0304; out of a total of 7970 normal beats, 1668 were classified as aberrant and eight were not detected. It can be argued that these incorrectly classified beats should not be used in the ischemic episode detection process, because, even though they have a normal origin, they present a morphology that is excessively distorted. As our system detects ischemic episodes rather than rhythm abnormalities, labelling normal beats as abnormal is not a serious error as compared to classifying no-normal beats as normal.

4.3. Validation of the algorithm for the detection of ischemic episodes

Before presenting the results of the validation of the ischemic episode detector, it is necessary to make some remarks. The criteria used for the detection of ST and T episodes are similar to those used during the annotation of the ESC DB. However, we have considered the relaxation of these criteria, managing to mimic the behaviour of the human expert in a more adequate manner. The main consequence of using a more flexible approach is the detection of extra episodes, which are not annotated in the database. This

Table 2
Partial validation of the beat classifier

Reference	Algorithm					
	n	v	f	q	o	x
Record e0103						
N	6167	0	0	740	1	0
V	0	0	0	70	12	0
F	0	0	0	2	0	0
Q	0	0	0	0	0	0
O	0	0	0	0		
X	0	0	0	0		
Record e0206						
N	10148	0	0	85	47	0
V	1	0	0	129	28	0
F	0	0	0	0	0	0
Q	0	0	0	0	0	0
O	0	0	0	43		
X	0	0	0	0		
Record e0207						
N	6803	0	0	60	24	0
V	0	0	0	30	0	0
F	0	0	0	0	0	0
Q	0	0	0	0	0	0
O	0	0	0	16		
X	0	0	0	1		
Record e0213						
N	9706	0	0	572	29	0
V	0	0	0	271	1	0
F	0	0	0	0	0	0
Q	0	0	0	0	0	0
O	0	0	0	9		
X	0	0	0	9		
Record e0304						
N	6294	0	0	1668	8	0
V	0	0	0	54	1	0
F	0	0	0	0	0	0
Q	0	0	0	0	0	0
O	0	0	0	32		
X	0	0	0	0		

N, normal beat; V, ventricular beat; F, fusion of ventricular and normal beat; Q, non classifiable beat; X, a pseudo-beat label generated during a segment marked as unreadable; and O, a pseudo-beat label generated at any other time.

is the case for some minor ST–T changes, which are ischemic but not considered significant with respect to the established thresholds. Thus, the performance with respect to the database annotations may be an underestimate of the true performance.

Given these considerations, instead of taking the annotations of the ESC DB as definitive, we have consulted an expert to assess the results obtained from applying our ischemia episode detector to recordings in this database. The expert judged the probability of the episodes which were detected, but not labelled as such in the database, being ischemic episodes.

Although we detected both ST and T episodes, only the detection of ST episodes was validated, mainly because the clinical significance of T wave changes is not well established. In the validation process, the set of 90 recordings from the ESC DB was divided into two subsets: one for training, which comprised 30 recordings and a test set of 60 recordings. The training set was used for determining the optimum value of the threshold for the certainty degree associated with the detection of an ischemic episode ($\mu_{e_{ST}}$). This threshold appears to be different depending on whether we consider gross (89%) or average (73%) statistics (see Fig. 9). In any case, high values for this threshold indicate that in general, only episodes that would have been detected by directly applying the criteria established by the creators of the database will be detected, as would be expected. In Table 3 we present the results from validating the algorithm over the test set, taking as reference the annotations present in the database and considering a threshold of 73% (optimal for average statistics). Our algorithm correctly detected 142 of the 171 episodes annotated in the database with 66 false positives, leading to a sensitivity of 83% and a positive predictivity of 75%.

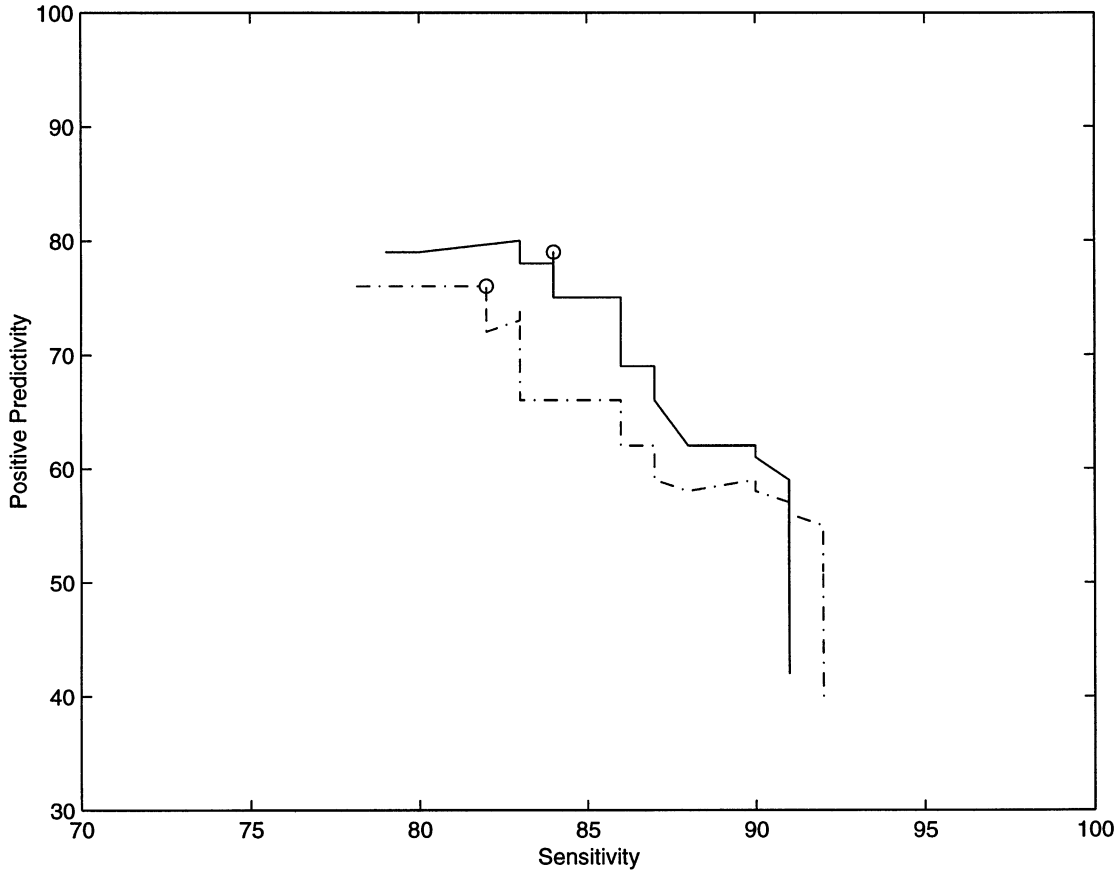

Fig. 9. 'ROC curves' corresponding to average statistics (solid line) and gross statistics (dashed line). The circles in both cases identify the optimal working point (point at which the Euclidean distance to the origin is maximum).

Similar or slightly better results have been obtained with other approaches for the detection of ischemic episodes which have also been validated with the ESC DB. However, some comments must be made regarding the type of validation carried out, the reliability of the annotations of the ESC DB and the advantages derived from our approach. Jager et al. [21,22] presented results of the validation of an algorithm based on the use of the Karhunen–Loève transform. They obtained a sensitivity and positive predictivity over the whole database of more than 80%. They do not indicate whether part of the recordings in the ESC DB have been used in the training stage. Silipo and Marchesi [23] obtained a sensitivity of 76% and a positive predictivity of 85% using a recursive neural network. These results are comparable to ours. Finally, Taddei et al. [24], by means of a geometric method and after using 40 out of the 90 recordings as a training set, report a sensitivity and positive predictivity of 84 and 81%, respectively. These authors indicate the need for carrying out a revision of the recordings, as minor episodes are not labelled in the data base, while they are detected by the algorithm. A review improved the positive predictivity to 85%. This result has led Taddei et al. to start the development of a new reference data base [25].

Table 3
Results from validation of the algorithm on a test set with a threshold of 73%

Ischemic ST detection, both signals						
Record	TPs	FN	TPp	FP	ESe	E+P
e0104	3	0	3	0	100	100
e0105	7	0	7	1	100	88
e0106	6	1	5	4	86	56
e0110	2	0	2	0	100	100
e0113	7	0	7	1	100	88
e0116	2	0	2	1	100	67
e0123	3	0	2	0	100	100
e0124	6	0	7	1	100	88
e0125	4	0	4	0	100	100
e0126	1	0	1	3	100	25
e0127	3	1	3	0	75	100
e0129	4	0	4	0	100	100
e0133	0	0	0	3	—	0
e0136	5	1	5	2	83	71
e0139	1	0	2	0	100	100
e0147	4	0	4	0	100	100
e0148	3	1	3	0	75	100
e0151	2	0	2	0	100	100
e0154	0	1	0	1	0	0
e0159	1	0	1	0	100	100
e0161	1	0	1	3	100	25
e0163	0	1	0	0	0	—
e0202	3	0	4	0	100	100
e0203	2	0	2	1	100	67
e0204	2	0	2	0	100	100
e0206	3	0	3	0	100	100
e0210	1	0	1	0	100	100
e0211	2	0	2	0	100	100
e0212	1	0	1	0	100	100
e0302	4	1	4	2	80	67
e0304	1	0	1	6	100	14
e0305	1	0	2	4	100	33
e0403	2	1	2	0	67	100
e0404	1	2	1	0	33	100
e0405	4	1	4	1	80	80
e0406	2	0	2	1	100	67
e0409	1	0	1	0	100	100
e0410	2	0	2	0	100	100
e0411	1	0	2	0	100	100
e0413	1	0	1	0	100	100
e0417	1	2	1	0	33	100
e0418	1	3	1	0	25	100
e0509	0	0	0	2	—	0
e0601	2	0	2	2	100	50
e0602	4	1	2	3	80	40
e0603	3	1	3	1	75	75
e0604	8	4	8	0	67	100
e0606	1	0	1	2	100	33
e0607	3	0	4	1	100	80
e0609	1	1	1	0	50	100
e0610	1	0	1	0	100	100
e0611	0	0	0	2	—	0
e0613	4	3	5	5	57	50
e0615	1	0	1	3	100	25
e0704	3	0	3	3	100	50
e0808	4	0	4	6	100	40
e0817	1	1	1	0	50	100
e0818	0	3	0	0	0	—
e1301	1	1	1	0	50	100
e1302	1	1	1	1	50	50
Sum	139	32	142	66		
Gross					81	68
Average					83	75

A summary of results from 60 records are shown. The threshold is an optimal value for average statistics. Both the sensitivity and positive predictivity are presented (ESe and E+P).

We performed a review of a set of 12 recordings and found that there is a large number of episodes whose certainty degree is lower than the threshold obtained in the training process. For these recordings, the best results were produced with a threshold of 51% (Table 4) giving a sensitivity and positive predictivity of 84 and 90%, respectively. Once again it should be noted that in many cases, ST segment amplitude values that are clinically relevant for one patient may not be relevant for another, depending on the previous clinical history. This makes it almost impossible to develop an algorithm that attempts the detection of all the ischemic episodes present in the electrocardiographic signal and for this reason we consider our approach to be adequate, as it permits the thresholds for each case to be set individually.

In order to verify the reliability of our algorithm with respect to the presence of

Table 4
Results from validation using a test set of 12 revised records for a threshold of 51%

Ischemic ST detection, both signals						
Record	TPs	FN	TPp	FP	ESe	E+P
e0110	2	0	2	0	100	100
e0123	3	0	2	0	100	100
e0129	4	0	4	1	100	80
e0151	2	0	2	0	100	100
e0154	0	1	0	3	0	0
e0163	1	0	1	0	100	100
e0202	4	1	4	0	80	100
e0204	2	0	2	0	100	100
e0206	3	0	3	0	100	100
e0211	2	0	2	0	100	100
e0403	2	4	2	0	33	100
e0411	1	0	2	0	100	100
Sum	26	6	26	4		
Gross					81	87
Average					84	90

A summary of results from 12 records is shown. The threshold is an optimal value for average statistics.

false positives, we analysed a set of 23 half-hour signals from young normal subjects from the Politecnico Cà Granda Database included in the biomedical signal CD-ROM of the Politecnico di Milano [26] with our system. Only three false positive episodes were detected with a very low certainty degree: 2, 10 and 16% respectively, all with a duration of less than 45 s.

It is important to note that this validation not only tests the algorithms for the detection of the ischemic episodes, but also all the previous stages (beat detection, feature extraction, etc.). The satisfactory functioning of our ischemic episode detector can be seen to be strongly compromised if other low level tasks that provide information to this algorithm do not work adequately.

5. Evaluation of the user-system interface

In a system such as the one proposed, the design of an adequate user interface is crucial. The success of the system in the environment for which it was designed will largely depend on it. We have based our assessment of the acceptance and usefulness of the interface on a methodology proposed by Ravden and Johnson [27], a questionnaire in which each one of the questions is based on a criterium or objective that any 'well designed' interface must meet. The questionnaire analyses the following features of the interface: visual clarity, consistency, compatibility, information feedback, explicitness, appropriate functionality, flexibility and control and error prevention and correction.

Each of these sections is made up of 6–12 questions, plus a global qualification question regarding the criterion it represents. The questionnaire was presented to five prospective users of the system (medical and paramedical staff of the General Hospital of Elche) and to five experts in the design of computer applications who did not participate in the design and development of the system. Before asking them to answer the questionnaire, a number of tasks that one would normally perform with the system were suggested to the users. These tasks involved most of the interaction resources present in the interface.

For the interpretation of the results of the questionnaires it was necessary to differentiate the aspects that are almost exclusively attributed to the graphic environment used in the development of the application from those concerning the application itself. For example, questions related to visual clarity, consistency or compatibility have much more relevance to the X11 windows system, than with the application itself. The acceptance and diffusion of this graphic environment

guarantees good results in these criteria, which reinforces our choice of interaction platform.

Since only a small number of people participated in this study, we present only global conclusions. On average, the users gave a moderately high score for the satisfaction index. Somewhat surprisingly, the computer applications experts were more critical than the clinical users of the system. The latter, in general, evaluated the system more positively, which implies a better guarantee of acceptance in the environment where the system must be installed. These results lead us to install the system without modifications, which will however need to be carried out according to the results after more intense use.

6. Conclusions

We have implemented a real time monitoring system aimed at the detection of ischemic episodes in ECG recordings. It performs a series of tasks, described in this paper, which result in a set of parameters such as, for example, the deviation of the ST segment and the amplitude of the T wave of the normal beats present in the electrocardiographic signal.

The evaluation of the system on the ESC DB database showed that our fuzzy approach for the detection of ischemic episodes is adequate. One of the features most appreciated by the cardiologists was the presence of a gradation of the relative confidence in the result, which emerges as a consequence of the degree of imprecision in the knowledge. In addition, the fuzzy rule approach greatly facilitates the redefinition of the criteria (even in real time) by modifying the definition of the associated possibility distributions.

One of the important and particularly useful aspects of our approach is that its computational complexity is not very high and thus its real time implementation is feasible. The real time monitoring of patients with ischemic cardiopathies clearly adds versatility to the treatment of these cardiopathies which cannot be obtained by using other off line monitoring techniques such as, for example, Holter monitoring. Even though there are other techniques which offer a similar performance to that obtained by our system [28,29], they are not usually suitable for real time implementation, unless specific hardware is used.

The design of a good user interface is of vital importance if the system is to be accepted by the user community for which it is designed. For this reason, even though the greatest emphasis was placed on signal processing, this aspect of the system was not forgotten. This is reflected in the very positive evaluation of the user-system interface implemented.

Finally we observe several clear lines of future developments. Until now we have not taken into account the possibility that sudden changes in the morphology of beats that originate in the sinusal node are a consequence of the motion of the patient [28]. This is an aspect we will try to solve in the future through a more sophisticated morphological classification of the beats. It should detect each new normal morphology, so that if a change of morphology coincides in time with a brusque change in the trend diagrams of the deviation of the ST segment or the height of the T wave, it must not be interpreted as an ischemic episode.

Another interesting field of work consists in trying to relate ischemic episodes with the appearance of particular previous cardiac arrhythmias. It will be necessary to implement a module for the detection of arrhythmias that provides information to the module for the detection of ischemic episodes, making it possible to relate the presence of a new

episode with the temporal closeness of a previous arrhythmia.

Furthermore, the integration of information coming from signals other than ECG would be interesting (for instance, invasive cardiovascular pressure signals). This integration may aid the process of detecting and characterising ischemic episodes.

Acknowledgements

This work has been supported by the Spanish CICyT and Xunta de Galicia under projects TIC95-0604 and XUGA 20602A97, respectively. We also wish to express our thanks to the referees of this paper for their detailed comments.

References

[1] B. Surawicz, ST-segment, T-wave and U-wave changes during myocardial ischemia and after myocardial infarction, Can. J. Cardiol. A (1986) 71A–84A.

[2] Siemens, The Sirecust 960/961 system. User's manual, Siemens.

[3] Marquette, Solar 7000/8000 patient monitor. Operator's manual, Marquette Electronics, 1995.

[4] S. Nelwan, S. Meij, L. Lundström, T. van Dam, P. Gilman P, M.L. Simoons, Continuous 12 lead ST monitoring, Comput. Cardiol. 23 (1996) 477–480.

[5] J. Presedo, Monitorización inteligente de isquemia en SUTIL, Ph.D. Dissertation, Servicio de Publicacións e Intercambio Científico, University of Santiago de Compostela, ISBN: 84-8121-160-5, 1994 (in Spanish).

[6] W. Fischer, IEEE P1014—A standard or the high-performance VME bus, IEEE Micro. 2 (1985) 31–41.

[7] H.V. Pipberger, R.C. Arzbaecher, A.S. Berson, S.A. Briller, D.A. Brody, N.C. Flowers, D.B. Geselowitz, E. Lepeschkin, G.C. Oliver, O.H. Schmitt, M. Spach, Recommendations for standardization of leads and of specifications for instruments in electrocardiography and vectorcardiography, Report of the Committee on Electrocardiography, Am. Heart Assoc. Circ. 52 (1975) 11–31.

[8] O. Pahlm, L. Sörnmo, Software QRS detection in ambulatory monitoring—a review, Med. Biol. Eng. Comput. 22 (1984) 289–297.

[9] The CSE Working Party, Recommendations for measurement standards in quantitative electrocardiography, European Heart J. 6 (1985) 815–825.

[10] P. Laguna, R. Jané, P. Caminal, Automatic detection of wave boundaries in multilead ECG signals: validation with the CSE database, Comp. Biomed. Res. 27 (1994) 45–60.

[11] J. Vila, J. Presedo, A. Bugarín, S. Barro, R. Ruiz, F. Palacios, Application of synctactic processing to ECG analysis, 12th International Congress on Medical Informatics, MIE-94, 1994, 579–584.

[12] A. Taddei, G. Distante, M. Emdin, P. Pisani, G.B. Moody, C. Zeelenberg, C. Marchesi, The European ST–T Database: standard for evaluating systems for the analysis of ST–T changes in ambulatory electrocardiography, Eur. Heart J. 13 (1992) 1164–1172.

[13] P.M. Rautaharju, S.H. Zhou, S. Wong, R. Prineas, G.S. Berenson, Functional characteristics of QT prediction formulas. The concepts of QT_{max} and QT rate sensitivity, Comp. Biomed. Res. 26 (1993) 188–204.

[14] J. Presedo, J. Vila, S. Barro, F. Palacios, R. Ruiz, A. Taddei, M. Emdin, Fuzzy modelling of the expert's knowledge in ECG-based ischaemia detection, Fuzzy Sets Syst. 77 (1996) 63–75.

[15] J. Presedo, J. Vila, M. Delgado, S. Barro, P. Palacios, R. Ruiz, A proposal for the fuzzy evaluation of ischaemic episodes, Comput. Cardiol. 22 (1995) 709–712.

[16] L.A. Zadeh, Fuzzy sets, Inf. Control 8 (1965) 338–353.

[17] P. Heinonen, Y. Neuvo, FIR-median hybrid filters, IEEE Trans. Acoust. Speech Signal Process 35 (1987) 832–838.

[18] S. Barro, R. Marin, J. Mira, A.R. Paton, A model and a language for the fuzzy representation and handling of time, Fuzzy Sets Syst. 61 (1994) 153–175.

[19] G.B. Moody, R.G. Mark, The MIT-BIH arrhythmia database on CDROM and software for use with it, Comput. Cardiol. 17 (1990) 185–188.

[20] AAMI Recommended Practice, Testing and reporting performance results of ventricular arrhythmia detection algorithms, Association for the Advancement of Medical Instrumentation, 1987.

[21] F. Jager, G.B. Moody, A. Taddei, R.G. Mark, Performance measures for algorithms to detect transient ischemic ST segment changes, Comput. Cardiol. 18 (1991) 369–372.
[22] F. Jager, R.G. Mark, G.B. Moody, S. Divjak, Analysis of transient ST segment changes during ambulatory monitoring using the Karhunen–Loève transform, Comput. Cardiol. 19 (1992) 691–694.
[23] R. Silipo, C. Marchesi, Composite neural network architecture for extensive long term ECG analysis, Comput. Cardiol. 23 (1996) 13–16.
[24] A. Taddei, G. Costantino, R. Silipo, M. Emdin, C. Marchesi, A system for the detection of ischemic episodes in ambulatory ECG, Comput. Cardiol. 22 (1995) 705–708.
[25] A. Taddei, M. Emdin, M. Varanini, G. Nassi, M. Bertinelli, C. Carpeggiani, E. Picano, C. Marchesi, A new cardiovascular signal database for assesing methods for analysis of ischemic heart disease, Comput. Cardiol. 23 (1996) 497–500.
[26] F. Pinciroli, R. Rossi, ECG and Resp from young normal subjects. A biomedical signals database on CD-ROM from the Politecnico di Milano.
[27] S.J. Ravden, G.I. Johnson, Evaluating Usability of Human–Computer Interfaces: A Practical Method, Ellis Hoorwood, Chichester, UK, 1989.
[28] A. Taddei, M. Varanini, A. Macerata, M. Emdin, C. Marchesi, Detection of ischemic episodes through principal component analysis, Biotelemetry 12 (1992) 77–84.
[29] T. Stamkopoulos, M. Strintzis, C. Pappas, N. Maglaveras, One-lead ischemia detection using a new backpropagation algorithm and the European ST–T Database, Comput. Cardiol. 19 (1992) 663–666.

.