A Fuzzy Logic Approach for a Wearable Cardiovascular and Aortic Monitoring System

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Abstract. A new methodology for fault detection on wearable medical devices is proposed. The basic strategy relies on correctly classifying the captured physiological signals, in order to identify whether the actual cause is a wearer health abnormality or a system functional flaw. Data fusion techniques, namely fuzzy logic, are employed to process the physiological signals, like the electrocardiogram (ECG) and blood pressure (BP), to increase the trust levels of the captured data after rejecting or correcting distorted vital signals from each sensor, and to provide additional information on the patient's condition by classifying the set of signals into normal or abnormal condition (e.g. arrhythmia, chest angina, and stroke). Once an abnormal situation is detected in one or several sensors the monitoring system runs a set of tests in a fast and energy efficient way to check if the wearer shows a degradation of his health condition or the system is reporting erroneous values.

Keywords: Electrocardiogram • wearable • fuzzy logic • dependability

1 Introduction

Along with the progress of medical technologies, many countries are gradually becoming geriatric societies due to the rapid growth of the aging population. This increases the need for home health monitoring for securing independent lives of patients with chronic disorders or that have health care problems. The advances on sensors, wireless communications and information technologies have resulted in the rapid development of various wellness or disease monitoring systems, which enable extended independent living at home and improve the quality of life. Traditionally, clinical practice has been based on a post-diagnosis intervention basis (drugs, surgeries, prosthesis, etc.). Nowadays, and regardless of the patients' age, the health care community is trying to focus on prevention and wearable monitoring systems have been proposed to meet this task. Therefore, diseases tend to be prevented, rather than treated, after continuous vital signals monitoring, which provide information about the health status related with lifestyle and overall quality of life [1-3].

Remote health monitoring can be used only if the monitoring device is based on a comfortable sensing interface, easy to use and customizable. Its interface must allow continuous remote control in a natural environment without interference or discomfort for the users. The textile approach to the implementation of sensing elements embedded in clothing items, allows for low-cost long-term monitoring of patients and to easily customize the sensor configuration according to the needs of each individual [4]. Applying this concept, it is possible to reduce health care costs maintaining the high quality of care, shift the focus health care expenditures from treatment to prevention, provide access to health care to a larger number of patients, reduce the length of hospital stays and address the issue of requirements for elderly population and/or chronically ill patients. It also allows accessibility to specialized professionals through telemetry, thus decentralizing the provision of health care.

Because these wearable monitoring systems are to be used for medical purposes (continuous monitoring, diagnosis, etc.), the reliability and safety of the system have to be perfectly controlled. Unfortunately, the complexity of these systems endlessly increases, making the existing techniques for dependability developed in aeronautics, space and automotive fields not totally appropriate for the medical case.

To overcome the lack of a dependability model for the development of complex pervasive medical monitoring devices, a fault tree analysis approach is used to identify the main risk of failure (see Fig. 1). A typical wearable device (hereafter the system) comprises a module to capture the biosignals, including the electrodes and the analogue front-end, a microcontroller, and a radiofrequency emitter to transmit the signal to a smartphone or a personal computer. In our approach the captured biosignals are received and analyzed within a smartphone. A rule based algorithm (fuzzy logic) decides whether the signals are normal or not. If not, it is diagnosed if the wearer shows an abnormal situation or instead the system is faulty. That is, the abnormality detected within the biosignals can be due to a wearer irregular state (pathological condition or intense physical activity) or due to a degradation of the system operation.

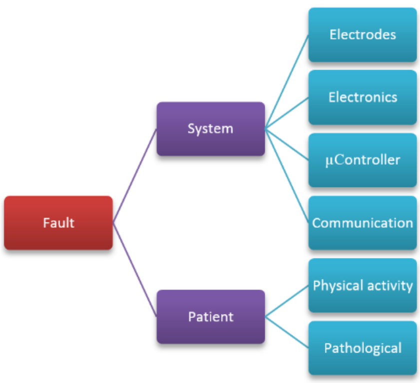

Fig. 1. Fault tree analysis of the wearable monitoring system.

2 Combined Cardiac and Aortic Monitoring System

The combined cardiac and aortic monitoring system (SIVIC system) under development (Fig. 2) provides the synchronous measurement of the patient ECG (electrocardiogram) and of the pressure in the abdominal aneurysm sac, in order to have a more robust and reliable monitoring. Biologically compatible wireless pressure sensors, which show suitable linearity and sensitivity [5], are used to capture the intra-sac aneurysm pressure. An electronic readout unit (ERU) capable of energizing the pressure sensors and capture the pressure data is placed in the chest of the patient. This unit provides also the monitoring of a 12-lead ECG using textile dry electrodes [6]. The electronic unit and the electrodes are built in a customized clothing.

Data is transmitted to a smartphone for further processing, data display, and eventual communication with a healthcare center.

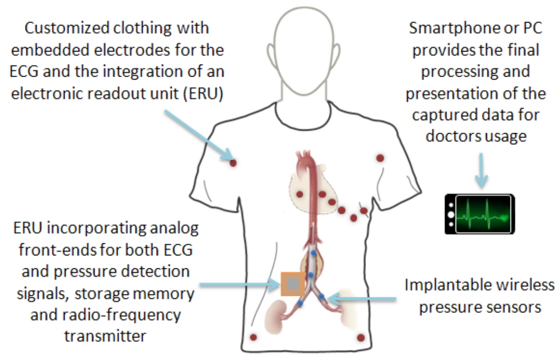

Fig. 2. Wearable ECG data capture and transmitter module.

The 12-lead ECG data acquisition and transmission (DAT) module prototype that was developed is a circular board (30 mm Ø) with an ECG acquisition analogue front-end based on the low-power (0.75 mW/channel) Texas Instruments 24-bit ADS1298 chip and a PAN1740 Bluetooth Low Energy (BLE) module from Panasonic. The board includes also an I2C EEPROM and a DC/DC converter to supply a regulated 3.3 V. The PAN1740 is a small (9 x 9.5 x 1.8 mm) BLE single mode module based on the Dialog DA14580 SoC with an advertised power consumption of 4.9 mA when transmitting/receiving. This SoC includes a 32 bit ARM Cortex M0 microcontroller (µC) operating at a 16 MHz frequency, that is used to perform all the necessary processing operations, thus saving the cost of an external µC, the additional PCB area and power consumption. The EEPROM is used to save the application code during the developing phase. In the final version it can be removed and the code can be saved in the One-Time Programmable (OTP) memory present on the BLE module.

Wireless ECG monitoring systems with a high number of leads (e.g. 12-lead) are usually designed for clinical usage, being systems with a lower number of acquisition channels (e.g. 1 to 3 leads) commonly used in ambulatory cases [7, 8]. Our system was designed having in mind its use in both clinical and ambulatory scenarios and thus the number of ECG data acquisition channels is reconfigurable. Inputs not used to capture ECG signals can be used to acquire other biosignals. Figure 3 shows the T-shirt cardiac monitoring system being proposed.

Fig. 3. The SIVIC T-shirt and data acquisition module.

3 Data Fusion for Diagnosis

The ECG contains important hemodynamic information, such has the heart rate (HR). During an ECG cycle three main events take place: the P wave (contraction of the atria), the QRS complex (corresponding to the contraction of the left ventricle) and the T wave (relaxation of the ventricles). Their morphologies (amplitude and interval/segment length) will vary in accordance to the physiological condition.

The HR, given in beats per minute (bpm), is the interval between two consecutive R-waves in the QRS complex. Noise contamination such as baseline wander, power line interference, and muscle activities can corrupt the signal and reduce the clinical value of an ECG recording. Since wearable devices are more affected by noise, filtering of the ECG is a necessary pre-processing step to ensure a reduction of the noise components while preserving the QRS complex shape. The Pan-Tompkins algorithm is used for ECG filtering and the HR calculation [9].

The availability of different sensors in wearable systems allows for fusing the respective data to formulate better decisions from the captured data. Other biosignals, such as the blood pressure (BP), defined by the systolic (maximum) and diastolic (minimum) pressures, can provide important information about the patient condition, eventually affected by physical activity or diseases. Accelerometers enable tracking the wearer activity, i.e. if he is sitting, walking or running, which will influence the heart activity. The SIVIC system also includes an electrode-skin impedance measuring circuit, which allows detecting if the electrodes are connected to the patient or are loose/disconnected.

Signals that can be measured with the SIVIC system, the extracted features, and the patient/system condition inferred from the respective classification are summarised in Table 1.

Table 1. Data fusion model for the measured signals.

Signals	Features	Classifier
ECG	HR I HR II HR III ⋮	Normal/Abnormal
Blood Pressure	Systolic Diastolic	Hypotensive/Normal/Hypertensive
AAA Sac Pressure	Mean Pressure	Endoleak
Accelerometer	Motion	Resting/Walking/Running
Electrode-Skin Impedance	Resistance	Connected/Disconnected

Data fusion techniques have been applied as a means for a combined analysis of several physiological signals that can potentially provide additional information on a patient's condition. Kenneth et.al performed the fusion of ECG, blood pressure, saturated oxygen content and respiratory data for achieving improved clinical diagnosis of patients in cardiac care units [10].

Table 2. Fusion rules for patient condition diagnosis.

Signals	Condition	Rule	
ECG	Normal Asystole Extreme Bradycard Extreme Tachycardia	HR between 60 and 100 bpm No QRS for at least 4 seconds HR lower than 40 bpm for 5 consecutive beats HR higher than 140 bpm for 17 consecutive beats	
Blood Pressure (mmHg)		Systolic	Diastolic
	Normal	90-139	60-89
	Hypotension	<90	<60
	Hypertension	>140	>90
AAA Pressure	Normal Endoleak	Low pressure (~40 mmHg) Sistemic pressure	

In our case, as a first approach, a fuzzy logic system is used for the data fusion due to its probability assignment based on rules. Since the values of the features extracted from the biosignals can be assigned in regions well defined in the medical literature, the rules creation is relatively straightforward (Table 2).

3.1 Fuzzy Logic

The fuzzy logic system comprises 4 main components: fuzzy rules (knowledge base), fuzzy sets, fuzzy inference engine and defuzzification (Fig. 4) [11]. The inputs of the fuzzy logic system are the features previously extracted from the measured signals (Table 1). The outputs are the *Patient Status*, *System Status* and the *Global Status*, which can be normal or faulty - i.e., either the patient has a health condition or the monitoring system is malfunctioning. The outputs are determined based on the input values of the fuzzy sets and the assigned rules for each output. The rules to define the Patient Status are based on medical information, here collected from the literature, the rules for the *System Status* are defined from the system specifications, and the rules for the *Global Status* include both.

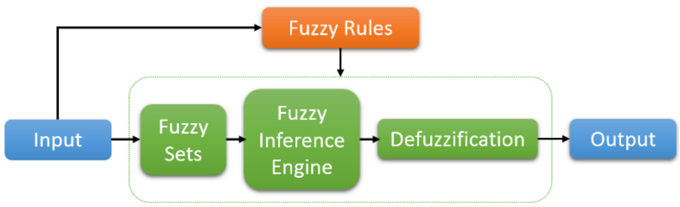

Fig. 4. Block diagram of fuzzy logic system.

The fuzzy sets include the HR for each channel, the blood pressure (systolic and diastolic), and can also include the contact resistance and the acceleration if these data are available.

The trapezoidal curve was chosen for the membership function. This is a function of a vector, x, and depends on four scalar parameters *a*, *b*, *c*, and *d* (equation 1). The parameters *a* and *d* locate the "feet" of the trapezoid and the parameters *b* and *c* locate the "shoulders".

$$\mu_{trapezoidal}(x) = \begin{cases} 0, & x < a \text{ or } x > d \\ \dfrac{x-a}{b-a}, & a \le x \le b \\ 1, & b \le x \le c \\ \dfrac{d-x}{d-c}, & c \le x \le d \end{cases} \tag{1}$$

Table 2 shows the normal values for the HR and BP, and some examples of pathologies.

4 Results

Data from the MIT Multiparameter database (MGH/MF) was used to test the fuzzy logic system using Matlab [12, 13]. The features from ECG signals (leads I, II and V) and the arterial blood pressure (ART) were extracted and feed to the fuzzy logic system. The ECG provides the HR information and the ART waveform is used to know the systolic and diastolic pressures.

The fuzzy logic was evaluated for 3 situations:

1) The recorded signals have good quality, i.e. the signal-to-noise-ratio (SNR) is good enough to identify relevant features, but the patient's blood pressure is very high (record MGH085 from the MGH/MF database). The System Status is ok, but the Patient Status indicates a health problem. Result: Patient Status: 14; System Status: 86; Global Status: 86.
2) Atrial flutter, or arrhythmia, is an abnormality of the heart rhythm resulting in a rapid and sometimes irregular heartbeat. Atrial flutter is recognized on an ECG by presence of characteristic flutter waves at a regular rate of 240 to 440 beats per minute (Fig. 5). In this case the HR is calculated using lead V, and the ART waveform is also used for a more reliable HR estimation, since these signals are related. Result: Patient Status: 14; System Status: 86; Global Status: 86.

Fig. 5. MGH023 record: Atrial flutter. (Grid intervals: time 0.2 s, ECG 0.5 mV, ART 25 mmHg

3) Sinus tachycardia is a heart rhythm originating from the sinoatrial node with an elevated rate of impulses, defined as a rate greater than 100 bpm in an average adult. The calculated HR from each channel indicates the patient has tachycardia (MGH010 record) Result: Patient Status: 14; System Status: 86; Global Status: 81.

After validating the fuzzy logic system with a database that contains annotations from physicians, the SIVIC wearable system was used to acquire the ECG signal of lead I. The smartphone receives the acquired data via Bluetooth, filters the received signal and calculates the HR and SNR. These features (HR and SNR) are used by the fuzzy logic system to monitor the patient and the wearable system. When a degradation occurs in the patient or system, the smartphone detects the fault and requests for further tests to the monitoring system in order to determine the cause and, if possible, to correct the fault. Figure 6 displays ECG waveforms acquired with the SIVIC system. On the left side of the figure the ECG waveform presents a normal sinus rhythm. On the right side of Fig. 6 the ECG waveform is corrupted with noise and the monitoring system is unable to calculate a reliable HR, since the SNR is high. A possible cause for this situation is a loose electrode, which could be determined by measuring the electrode-skin impedance. Since this is a very common problem in wearable devices, the SIVIC system periodically records the impedance of the textile electrodes and stores this value for each user. When the problem in the signal was detected the smartphone sent a request to the SIVIC system to perform an impedance measurement, and received a value of 13.911 MΩ, which was much higher than the recorded impedance values for the wearer under observation (around 1 MΩ). In this situation the smartphone issues a warning for the user to readjust the electrodes embedded in the t-shirt.

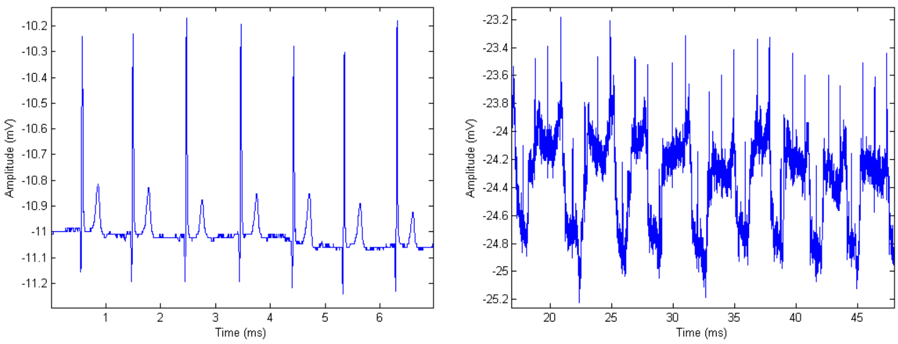

Fig. 6. Normal ECG (left side) and ECG corrupted with noise (right side).

5 Discussion

When the data fusion model detects that the System Status is degraded, further tests can be performed by the system to determine the cause. The smartphone sends an order for specific tests to be performed depending on the signals features. For instance if an ECG channel presents a behavior similar to the atrial flutter condition, but the remaining channels are normal, the cause of the flutter could be caused by the acquisition system, rather than the patient's heart. An oscillation in the ECG amplifier could cause such flutter in the signal. A simple test would be to connect both inputs of the amplifier and observe if the flutter persists. If not, it could be the case the signal is really displaying a health condition that is more visible in this particular ECG channel.

On the other hand, the data fuzzy model is flexible in the sense that further inputs can be added to the system- providing extra information regarding the patient and the system. For instance environmental sensors, like accelerometers, can be added to monitor the patient activity. If motion is detected at the same time the ECG signal is degraded, the system can determine the degradation of the biosignal as temporary and not related with any fault from the electronics or the electrodes.

6 Conclusion

The advances on sensors, wireless communications, and information technologies have promoted the rapid development of various wearable patient monitoring systems. The availability of wearable vital signals monitoring systems allows for securing independent lives of patients with chronic disorders or who require a permanent vigilance, while improving their daily quality of life. The work presented herein shows how data fusion, notably fuzzy logic, can be explored to improve the dependability of a cardiovascular monitoring wearable system, after providing a means to, on the fly, diagnosing whether deviations detected in the acquired signals are due to a disease or condition of the patient, or actually to a fault in the system. It is also a tool which can help, in the electronics design stage, the process of identifying test operations needed to improve the system's diagnosability.

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