Design and Testing of a Cardiac Monitor for Home Care

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Abstract

The aim of this paper is to discuss the design and testing of a new battery-powered cardiac monitor for Homecare. The device is able to acquire two ECG channels; these signals can be processed, stored and transmitted through a Bluetooth´s communication channel. The monitor is based on the MSP430F5438 microcontroller from Texas Instruments and includes a graphic LCD, a simple keypad, a two-channel ECG amplifier, and two NiMH batteries. The ECG is displayed in real time with the heart rate; QRS complexes are detected to compute heart rate. The QRS complex detection is based on an energy function. A new element was introduced in the ECG acquisition; an ECG channel can be acquired by holding with hands the device because its case has two embedded electrodes. On the other hand, the two ECG channels can be acquired by connecting the appropriated patient cable to the monitor. The method developed for QRS complex detection has been tested with twelve ECG strips from MIT-BIH annotated ECG database; 98.05% of the QRS complexes were detected and false positives were not present.

1. Introduction

Cardiac diseases are the leading cause of death worldwide, according to reports from the World Health Organization (WHO) and the data presented at the World Congress of Cardiology 2011. Statistics indicate that about 17.5 million people died in 2010 from this cause, accounting for 32% of all deaths worldwide. These figures can be reduced significantly with early detection of disease using innovative technologies [1].

Arrhythmias are one of the cardiac diseases with the highest incidence in the population. These pathologies usually are chronic and require a continuous follow-up, so it would be useful to have tools that facilitate the study of this kind of patients.

The development of Informatics and Communication has had a major impact on all spheres of life, including health care [2]. New services have emerged as the Telemedicine and Home Care that are intended to improve the quality of health services [3]. Technologies such as wireless communication and mobile telephony have facilitated the exchange of information and transmission of biomedical signals between portable devices (PDAs), cell phones, etc. and telemedicine centers without being constrained patient mobility. Based on these realities, there is a new range of medical equipment dedicated to outpatient use [4].

The aim of this paper is to discuss the highlight of the design and implementation of a portable cardiac device. It is able of acquiring two-channel of electrocardiogram (ECG), display them on a screen together with heart rate, and transmit this data by Bluetooth to another computer or system. This kind of cardiac device can be interface to a Telemedicine system or just to a computer for processing and storing. This kind of device can be used to form the acquisition layer in a Telecardiology system.

2. Materials and methods

For the design of the cardiac device proposed, the authors of this paper were considered as fundamental premises: patient safety, battery power to ensure adequate autonomy, the use of low power electronic components and minimum dimensions possible, including weight.

The electronic design is divided, from the point of view of their performance, in the following blocks: power supply, analog block and digital block.

The power supply block was designed to output all the voltages necessaries in the cardiac device proposed. Analogue components work with voltage level of -3.3 V and +3.3 V, while levels of +3.6 V and -3.6 V are used to power digital parts like the MSP430F5438 microcontroller, the LCD (Liquid Crystal Display) and the Bluetooth module. Two NiMH AA batteries supply 1.2 V and 2400 mAh.

An analogue block was designed to acquire the ECG, it is divided into a signal amplifier circuit and a circuit to check the electrode status. The amplifier consists of three stages by derivation consists of buffers to ensure high input impedance, AD627A instrumentation amplifier low power input and two non-inverting stages formed through OPA4336 operational amplifiers that guarantee the necessary gain. The total gain of the amplification steps is 308 to have an appropriate level to the digital block input and meet the dynamic range 5mV ± international standard set by the AAMI [5] [6].

Analogue filters were implemented to eliminate

interference signals and to set the frequency bandwidth. The effective bandwidth was set from 0.05 Hz to 50 Hz according to the international standards for monitoring devices. [7]. this range of frequency contains all the information needed to study the heart rhythm.

Another important part of the analogue block is the circuit to detect lead off. This circuit is formed by four pull-up resistors. When an electrode is disconnected, the voltage of four signals attached to the A/D converted is increased. This voltage values remains high until the electrode is properly connected. This condition is checked within the Timer_A interrupt service in order to reset the baseline with a recovery time of 50 ms, much less than the 3 seconds in the IEC standard.

The digital block guarantees the ECG digitization for subsequent processing, displaying, storage and transmission. It is mainly composed by a microcontroller, a graphical display, a membrane keyboard, a flash memory and a Bluetooth module.

The MSP430F5438 microcontroller from Texas Instrument was selected because of its very low power consumption and its high integration degree this microcontroller includes. It is a 16-bit RISC microcontroller including the following features: 256KB +512 B of Flash memory, 16KB of RAM, three timers for timing or counting events, three DMA channels and a twelve-bit analog to digital converter. Also, an analog multiplexer with twelve inputs was included in the electronic design in order to drive several signals; four serial ports integrated into the microcontroller are used for data communication.

The selected microcontroller integrates various peripherals (memory, ports, interrupts controller, etc.). This feature simplified the design of the proposed device because the amount of necessary electronic component was decreased. At the same time, the reliability of electronic design increases.

The LCD, from Orion Display Technology (ODT), is an important part of the device interface. It is used to show alphanumeric information and the digital ECG as part of the communication between the device and the patient. This LCD was selected taking into account its resolution, its input voltage and its displaying area. After a search over a large number of manufacturers, the selected model was the OGM-Model-F-KE050 128GB109G. It has a resolution of 128x64 pixels, is monochrome and has an 8-bit bidirectional bus data. The data is sent to the LCD using a parallel interface driven by the microcontroller.

The proposed device has flat a keypad. This technology was selected because of its low cost, simplicity for manufacturing and facilities provided for its cleaning. An integrated speaker was included in the electronic designed in order to sound when some abnormal conditions are present. Also, the device has a 64 Mbit flash memory; model AT45DB642D from Atmel,

which is used to store the digital ECG. The memory interface for read/write operations is based on the SPI protocol. Several I/O microcontroller lines are used to drive the speaker and the memory described previously.

LMX9838 Bluetooth module is based on a link controller (Link Manager) and baseband under the Bluetooth 2.0 specification in the radio frequency 2.4 GHz. This module includes the antenna, a RISC processor, a 16-bit EEPROM memory and RAM to support updates and / or operational improvements. Also, this module has serial port communication, advanced audio digital interface, power management with low power mode, low frequency oscillator (LFO), I/O general purpose lines, among others features.

The proposed device is powered by two NiMH batteries type AA. All the electronic components were selected to minimize the power consumption. Also a mechanism to drive the power supply was implemented. The largest power consumers are unplugged when not in use, thus autonomy of 48 hours was reached. A functional diagram of the proposed device is shown in Fig. 1.
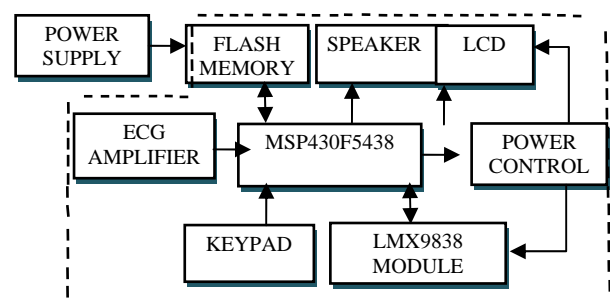

Figure 1. Structure of the proposed device.

When the device is power on, it checks if cable electrodes or embedded electrodes are connected to the patient. Analog interrupts choose the input signal to the ECG amplifier. Once this detection process is finished, the ECG is acquired and filtered to be displayed on the device LCD. QRS complexes are detected and heart rate is computed periodically. The acquired ECG is stored in the device memory to be transmitted lately. The acquisition period is set in the device setup; it can be changed anytime.

The first processing step is the ECG analog digital conversion; a twelve-bit A/D converter embedded into the microcontroller is used. The sampling rate is 250 Hz and a digital filter is applied avoid baseline wandering and to attenuate presence of noise.

A moving average filter proposed by Ligtenberg and Kunt [9] is applied as detailed in the expression 1. The filter must be based on integer coefficients because it will be implemented in real time. It is also necessary a FIR filter to ensure a linear phase distortion; mandatory for medical devices [10].

$$y(k) = \frac{1}{K^2} \sum_{m=k-K+1}^{k} \sum_{n=m-K+1}^{m} x(n) - \frac{1}{L^2} \sum_{m=k-L+1}^{k} \sum_{n=m-K+1}^{m} x(n) \qquad (1)$$

where:
x(n): input signal,
y(k): filtered signal,
K, L: filter constants

The cut-off frequencies are set to 0.6 Hz to 37 Hz in order to reduce the influence of electromyographic noise and to avoid baseline wandering. The filter expression seems too complex to be implemented in real time on a microcontroller, but it can be optimized easily.

An energy collector is computed continuously; it is used as an auxiliary function in QRS complex detection. it is known that these complexes are associated to the greater energy components in ECG [9]. 150-ms moving window is used for calculating energy and two thresholds are computed taking the maximum energy value as reference.

$$y(k) = \sum_{n=k-N+1}^{k} x(n) \qquad (2)$$

where,
y(k): energy value for sample k,
x(n): squared slope value for simple n,
N: width of integrator window.

An energy threshold is used to set the border between the signal that is associated with certainty to the QRS complexes and that does not meet this condition. The other threshold is used to identify the onset and offset of each detected complex. Between these instants, the maximum ECG value is located and used as an ECG fiducial point for calculation of the RR interval. It is very important to get a reliable heart rate value [11].

Energy thresholds are updated regularly so that the whole process automatically adjusts to changes that may have the electrocardiographic signal in a long-term recording.

The RR interval is measured for each QRS complex detected in order to compute the mean value of this parameter. The RR mean value is used to calculate the heart rate and to identify cardiac rhythm disturbances. A premature QRS complex is detected if the RR interval preceding it is less than 75% of the average RR interval [12]. This average value is updated every ten detected QRS complexes; maximum and minimum RR intervals are excluded to get this mean value. Thus is achieved an adequate level of exclusion of possible errors in the QRS detection.

The device firmware was programmed in C language for the MSP microcontroller family. All the algorithms were implemented using only integer arithmetic to facilitate the real-time execution.

Device operation is easy for the patient and is aimed at acquiring and transmitting ECG strips periodically, so that a doctor can assess whether a patient is responding appropriately to an antiarrhythmic treatment or not. Any cardiac event can be documented in the recorded ECG.

3. Results

The device design has been completed. It has been tested according to the IEC 60601-2-47 standard for ambulatory devices. The main results can be seen in table I.

Parameter	Result
Frequency response	0.05 to 60 Hz
Accuracy and stability of the sensivity	Less than +-5%
Recover time	50 ms
Common Mode Rejection	89 dB
Noise Level	30 uV
Crosstalk Interference	Less than 0.145 mV

The results were successful; the device performance meets the minimum values set for the standards for this kind of devices.

The QRS complex detection algorithm was preliminary with twelve ECG strips from MIT-BIH annotated database which is regarded as an international standard for such assessments.

Table 1. Sensitivity of QRS complex detection process.

ECG	QRS	QRS detected	%
100	2273	2218	97,58
103	2084	2033	97,55
105	2572	2561	99,57
106	2027	1996	98,47
108	1774	1751	98,70
112	2539	2488	97,99
123	1518	1483	97,69
208	2955	2901	98,17
209	3005	2959	98,47
210	2650	2594	97,88
230	2256	2187	96,94
Total	27518	26983	98,05

The results were satisfactory. Despite the considerable variety of QRS complexes present in the signals, 98,05% of these complexes were detected. A fact to note is that there were not false positives; it is very important since a false positive distort RR interval measurement and therefore it could conduce to a bad heart rhythm interpretation. False negative are always present; 100% effectiveness has not been reported for any real-time algorithm.

The evaluation of the embedded electrodes cannot be tested because the definitive plastic case of the device is not ready. However, this electrodes were evaluated acquiring ECG during five minutes in repeated tested and a baseline wandering was observed despite digital filter. This feature must be tested with better conditions in order to get its real performance.

To test the Bluetooth communication performance, a simulated ECG was transmitted to a computer during ten hours without interruptions; the received signal was stored in order to be compared with the original ECG. No differences were found between the received and transmitted signals.

4.   Conclusions

The design of a new ECG device for using at home was finished. It is an easy to use device oriented to make cardiac rhythm studies where patient live. A low-consumption electronic solution was achieved in order to ensure an adequate level of autonomy.

Bluetooth communication was stable and reliable according to the test results. This standard guarantees the ability to communicate with a large number of portable devices.

The algorithms used for ECG processing have been successful in tests. The microcontroller chosen was appropriated because it is able to support the ECG processing and device operation

References

[1] World Heart Organization. The World Heart Report 2008. at http://www.who.int/research/es/

[2] Eaton S. Handbook for Personal Caregivers of the Elderly. 2002 Bloomington, IN: 1st Books Library

[3] Rice R. Home Care Nursing Practice: Concepts and Application, 2005 3rd edition. Philadelphia: Mosby

[4] Conti M. The Handbook of Ad Hoc Wireless Networks. 2003 Chapter 1. CRC Press. ISBN 0-8493- 1332-5

[5] AAMI ECG Committee Performance Standard for Ambulatory electrocardiographs. Publication August, 2005.

[6] Webster JG. Médical Instrumentation Applications and Design. 2001Chapter 3, 256-258, 262

[7] Tompkins WJ. Biomedical digital signal processing. 2000 Prentice-Hall

[8] Konstantas D, Herzog R. Continuous monitoring of vital constants for mobile users: The mobihealth approach. EMBC. V 2003: 3728–3731.

[9] Ligtemberg A. A Robust QRS detector. Engineering in Medicine and Biology Journal 1993; 3: 272–279.

[10] Pietka. Feature extraction in computerized approach to the ECG analysis. Pattern Recognition 2001; 139-146.

[11] Tompkins WJ. Biomedical digital signal processing: C Language Examples and Laboratory Experiments for the IBM PC, 2003 Prentice-Hall

[12] González R. Análisis computadorizado de electrocardiogramas. Cuaderno de Engenharia Biomedica, 1997;13(3): 139-148.

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