ST's WELLNESS SOLUTION: RELIABLE HEART MONITORING

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ABSTRACT

The lifestyle of populations in urbanized and industrialized countries has led to a reduction in the level of individual physical activity. Reports of the World Health Organization (WHO) [4] indicate that more than 60% of the global population is not sufficiently active and that the numbers of sedentary people are now increasing in the emerging countries as well. Many medical experts affirm that this physical inactivity is the cause of many cardiovascular and diabetic diseases, called the metabolic syndrome. The most problematic country is the USA, where some studies estimate 25% of the population suffers from these conditions - obesity, elevated blood pressure, elevated fasting plasma glucose, high serum triglycerides, and low high-density cholesterol (HDL) levels [1].

INTRODUCTION

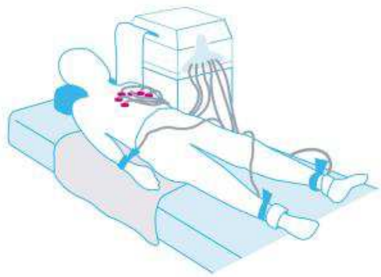
Surely, changing the day by day lifestyle is the first step to improve quality of life, but monitoring the healthy parameters and a specific nutrition program are becoming helpful to reduce hypertension, abnormal blood lipids, and obesity. This change in lifestyle is beneficial also to young people; in fact the American College of Sport Medicine (ACSM) has introduced some international guidelines [1] to be adopted in high schools. Otherwise, the number of hours of exercise per week decreases to a discouraging level when people approach middle-age. In fact, a middle-aged woman doing less than one hour of exercise per week doubles her chances of dying from a cardiovascular event compared to a physically active woman of the same age (see Figure 1).

Since monitoring life style and healthy parameters has become crucial for the correct diagnosis of patients, in this paper, the authors would like to introduce a new instrument able to monitor the heart and its indirect parameters.

Figure 1: ACSM recommends an improved quality of life

Healthcare expenses are increasing in all countries, and governments are faced with growing requests for preventative treatment before chronic and communicable diseases occur. This is evolving healthcare to the so called "wellness and self-empowerment of patients" [5]. Practically, the patients are no longer "passive" to the care indicated by doctor, but they are empowered to better their own care with the support of doctors. This generates an aware lifestyle that is also promoted by many nongovernmental and independent organizations.

Figure 2: Cart ECG Systems



This new scenario passes through an increasing number of Points of Care (PoC). Distributed in urbanized cities and in small villages, PoC is considered the first access point to the Public Health Organizations where people want to meet a medical staff equipped by the needed instrumentation for rapid diagnosis. Fundamental among these diagnostic services is Electrocardiography (ECG). Often the ECG in the PoC is the Computer-aided ECG; these are constituted of the analog part of a classical cart ECG (see Figure 2), which demands PC processing and display of data. With this hardware arrangement, the PC plays two important roles: easy storage and retrieval of ECG data and, administration and management of the data acquired.

Recent studies have proven that continuous feedback from periodic diagnosis increases a person's motivation to continue improving his lifestyle. Remote monitoring is the obvious solution to maintain a direct contact between personal doctors and their patients.

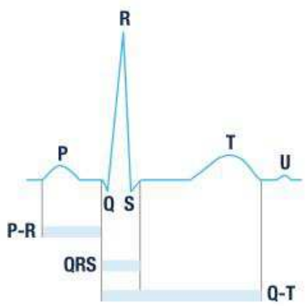
STMICROELECTRONICS' D-ECG SOLUTION

Electrodes are the sensors used to acquire ECG (see Figure 3); these convert ionic current flow in the living tissue to electronic current flow suitable for the Analog Front End of the electro-medical instrument. To understand the origin of bio-potential signals like ECG, we should consider the following:

1. Electrical activity at the cardiac cellular level and the extracellular potentials generated as the result of the electrical activity of single cardiac cells placed in a large homogeneous bathing medium with the same composition as body fluids.

2. Extracellular potentials generated as the result of the electrical activity of a large number of myocardial tissues placed in a large conducting medium with the ionic composition of body fluids.
3. The relationship between these extracellular potentials and the gross electrical activity recorded on the body surface as ECG signals.

Figure 3: ECG Waveform



These ECG signals have diagnostically significant frequency content between 0.05 and 250 Hz. To ensure perfect acquisition of signals, the Analog Front End has to guarantee amplification of the ECG signals and rejection of nonbiological (e.g. powerline noise) as well as extraneous biological interferences (e.g. EMG), to include a differential amplifiers with high gains and an excellent common mode rejection (CMMR) capabilities in the range of 80 – 120 dB.

In these ECG systems, computer memory, display screen and printing capabilities are dedicated to store and present the ECG data. Generally, the electrodes are placed on the body in fixed positions (see Figure 2), which are called lead connections (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6).

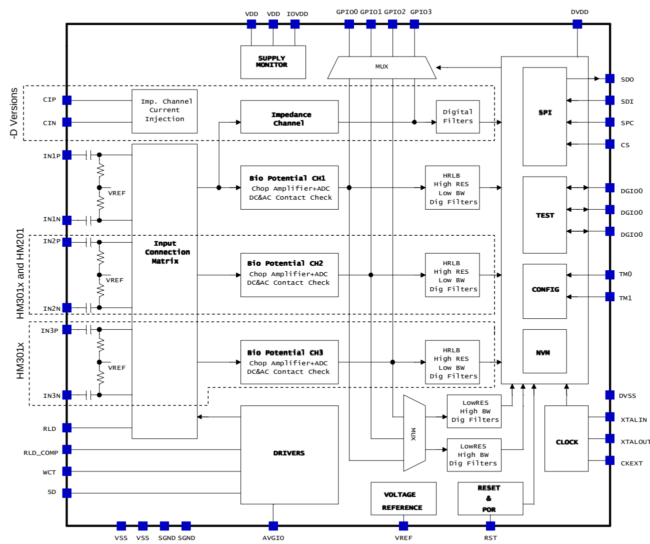
More specifically:

- Derivation I = RA – LA (right arm - left arm)
- Derivation II = RA – LF (right arm – left foot)
- Derivation III = LA – LF (left arm – left foot)
- aVR is obtained by right arm as
$$aVR = \frac{3}{2}(RA - V_{WCT})$$
- aVL is obtained by left arm
$$aVL = \frac{3}{2}(LA - V_{WCT})$$
- aVF is obtained by left leg
$$aVF = \frac{3}{2}(LL - V_{WCT})$$
- V1 is the difference between the electrode placed on 4^{th} intercostal space on the just to the right of the sternum and the V_{WCT}.
- V2 is the difference between the electrode placed on 4^{th} intercostal space on the just to the left of the sternum and the V_{WCT}.
- V3 is the difference between the electrode placed on interspace between V2 and V4 and the V_{WCT}.
- V4 is the difference between the electrode placed on 5^{th} intercostal space in the mid-clavicular line and the V_{WCT}.
- V5 is the difference between the electrode placed on 5^{th} intercostal space in the left axillary line and the V_{WCT}.
- V6 is the difference between the electrode placed on 5^{th} intercostal space in the midaxillary line and the V_{WCT}.

Where the V_{WCT} is a virtual reference called Wilson Central Terminal (WCT):

$$V_{WCT} = \frac{1}{3}(RA + LA + LL)$$

Figure 4: HM301D block diagram



The ST HM301D (see Figure 4) provides a suitable solution for the ECG signal acquisition by offering, in addition to the above mandatory features, a series of fully integrated and configurable digital band-pass filters that allow selective analysis of the ECG wave by physicians.

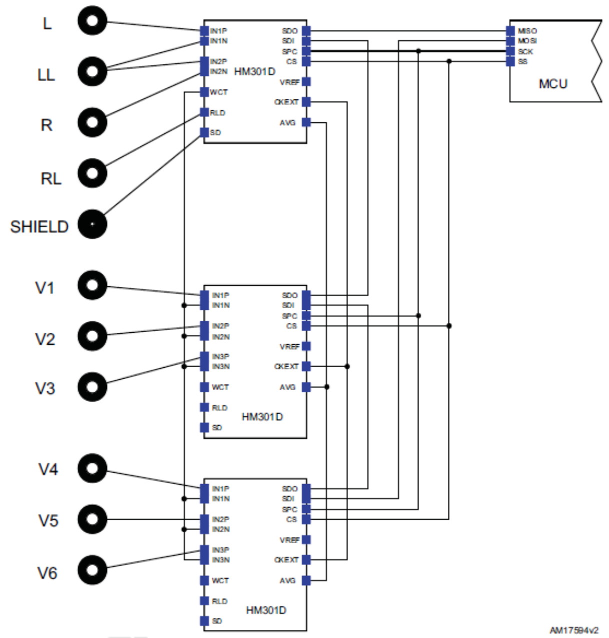
The filtered and processed data can be read through the SPI port. Each device includes three complete ECG differential channels and up to four devices can be connected in chain to implement multi leads ECG configurations (see Figure 5).

With about three million people worldwide using a pacemaker, it is mandatory, for a diagnostic type ECG device, to support the analysis of the pacemaker pulse. The HM301D has two dedicated pacemaker channels with a 10 kHz bandwidth and with adjustable pacemaker pulse detection.

Together with the ECG functions, the HM301D provides all the features to calculate body mass and respiration rate thanks to the fully integrated impedance measurement channel. The HM301D injects a small high frequency square wave current to the body through two of the electrodes used for ECG and measures the resulting voltage. IQ modulation/demodulation technique with digital band-pass filters provides real and imaginary parts of the time variant component due to respiration and a non-time variant component linked to the body mass.

Additional functions and features include Right leg Drivers, a WCT driver, a shield driver and an input connection matrix. Low supply voltage operation and low power make the device also suitable for battery operated equipment.

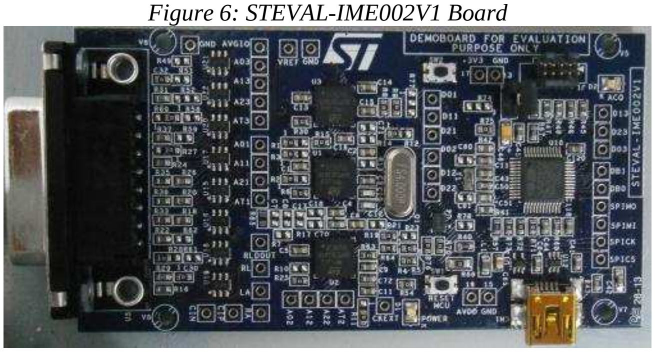
Figure 5: Multi chip configuration



HM301D Evaluation Boards: STEVAL-IME002Vx

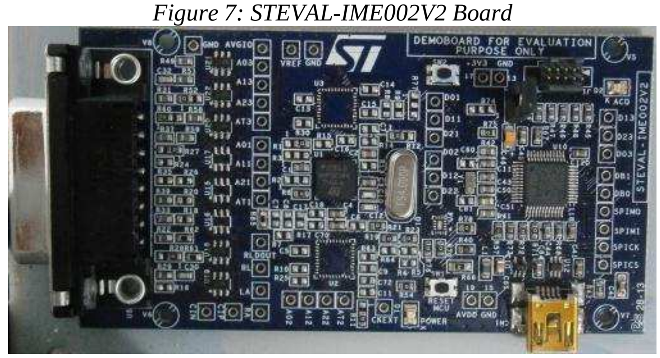
The STEVAL-IME002Vx is a family of evaluation boards designed around the new HM301D Diagnostic Quality Analog Front End for bio-electric sensors and bio-impedance measurements.

Figure 6: STEVAL-IME002V1 Board



This family of boards is composed of two evaluation boards: the STEVAL-IME002V1 and the STEVAL-IME002V2 respectively designed to demonstrate the use of HM301D in Electrocardiographs (or patient monitor systems) (ECG) and Automated External Defibrillator (AED) configurations. They also host a 32-bit microcontroller of the STM32 family that manages the SPI protocol of HM301D and the USB communication from/to the PC. Any board could be easily used with dedicated PC software Graphical User Interface to demonstrate all the different configurations.

Figure 7: STEVAL-IME002V2 Board

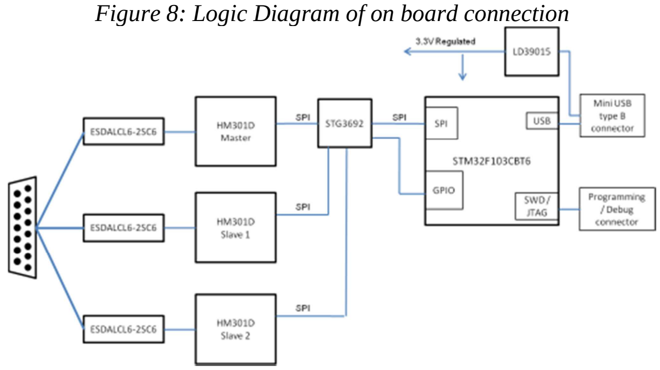


In order to optimize hardware development, the two boards are practically identical; the only difference lies in the mounted components, as is possible to appreciate comparing Figure 6 and Figure 7.

The STEVAL-IME002Vx demonstration boards have been designed to manage up to three HM301D devices in an SPI daisy chain. On the STEVAL-IME002V1, an STG3692 (low voltage high-bandwidth quad SPDT switch) manages the switch between the three possible configurations of one, two or three devices entitled U1, U2, and U3 on the board. Only daisy chain configurations are possible, in other words, it is not possible to have U2 and U3 active without U1. The allowable sequences are U1, U1 and U2, U1 and U2 and U3, in this order.

Any HM301D input is protected by an ESD protection device, the ESDALCL6-2SC6, compliant with the IEC61000-4-2 level 4 standard.

Figure 8: Logic Diagram of on board connection



The hardware block diagram, in Figure 8, illustrates the logical connections between all the components on the board, while Figure 10 shows the placement of components on the board.

Specifically, the logic connection between the STM32F103CBT6 peripherals and the HM301Ds is shown in Figure 9, where the master of the SPI is the STM32F103CBT6 microcontroller that manages the SPI switch path (through STG3692), closing the SDO signals to the MCU.

To evaluate the different modes of operation of the HM301D devices, the demonstration boards allow the connection of the first

HM301D (U1) in bipolar or unipolar configuration, while the other HM301Ds (U2 and U3) are always connected in unipolar mode.

Figure 9: SPI daisy chain

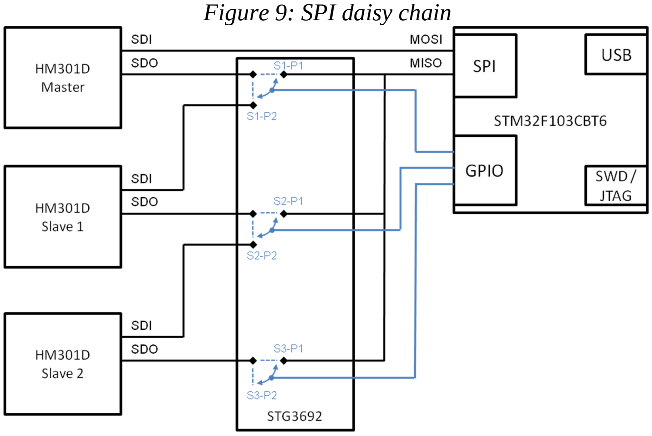


Figure 10: STEVAL-IME002Vx Board Layout

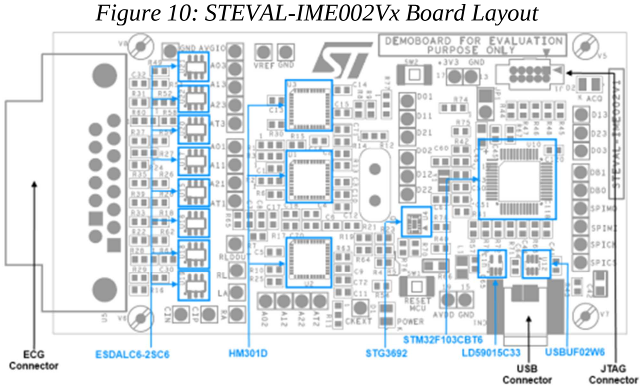


Table 1: Input Configuration of first HM301D based on Rx positioning

	STEVAL-IME002Vx configuration		Result
R1 U1 – IN1	1-2 (default in V1)	Unipolar mode	WCT shorted with IN1_P
	2-3 (default in V2)	Bipolar mode	LA shorted with IN1_P
R2 U2 – IN2	1-2 (default in V1, not mounted in V2)	Unipolar mode	WCT shorted with IN2_P
	2-3	Bipolar mode	LL shorted with IN2_P
R3 U1 – IN3	1-2 (default in V1, not mounted in V2)	Unipolar mode	WCT shorted with IN3_P
	2-3	Bipolar mode	RA shorted with IN3_P
R15	R0 in V1, not mounted in V2		LA shorted with IN2_N

Specifically on the STEVAL-IME002V1 board, U1 is configured to acquire the Einthoven equilateral triangle. Its vertices are LA (left arm), RA (right arm), and LL (left leg) and are directly connected to U1. Moreover, the RL (right leg) is used as a reference electrode for potential and is connected to pin 9 of U1. In this arrangement, the electrocardiographic frontal limb leads could be easily retrieved. In fact, lead I is the potential difference between LA and RA, lead II is the potential difference between LL and RA and, lead III is the potential difference between LL and LA. The connection is controlled by the resistors R1, R2, R3 and R15 (see Table 1).

Most traditional clinical ECG machines use a single channel amplifier and recording system with a multi-position switch to select the desired lead connection. The HM301Ds on the STEVAL-IME002V1 board permit the recording of all lead connections (I, II, III, V1, V2, V3, V4, V5, and V6) and apply them to the bio-potential amplifier through the parameter setting of a Graphical User Interface. The ECG leads can be also recorded on the user's PC.

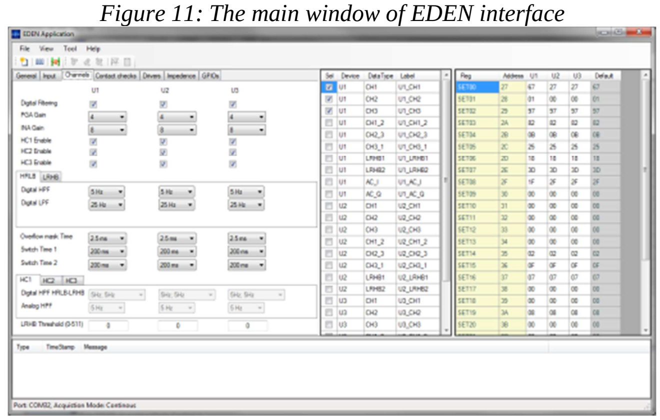
If present, the electrodes V1, V2 and V3 are connected to the U2 in unipolar mode and, the electrodes V4, V5 and V6 to the U3 in unipolar mode. All the connections of the U2 and U3 devices are unipolar and are referred to the WCT signal of the master (U1) device.

Specifically on the STEVAL-IME002V2 board, only U1 is mounted on the board, and it is configured to acquire only lead I, the potential difference between LA and RA.

Once configured however necessary as indicated in Table 1, the evaluation board is ready to be used. In fact, it is provided with STM32 firmware that is able to retrieve all the ECG signals from the HM301D and send them to a PC through the USB cable.

On the PC, there is available a Graphical User Interface (GUI) to set all the parameters of the ECG system (see Figure 11) and also plot the acquired waveform on the display screen (see Figure 12).

Figure 11: The main window of EDEN interface

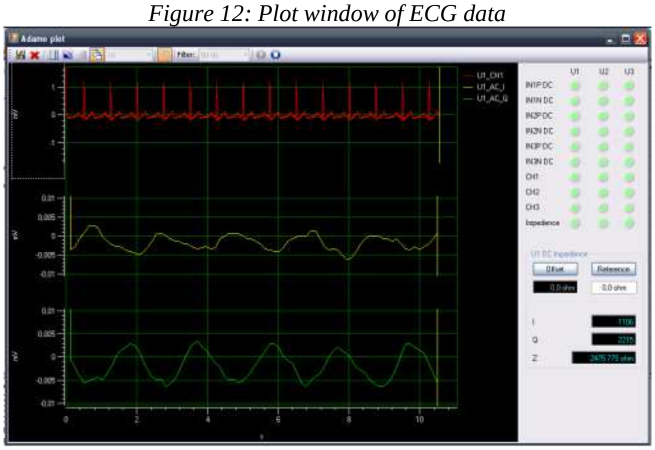


The user can easily print the ECG signals or save them to local disk for further analysis or post-diagnosis.

Moreover, the GUI also offers the possibility to retrieve the impedance channel of HM301D, which is able to measure the impedance of the body and measure variations due to respiration.

It is important to consider that the HM301D mounted on the STEVAL-IME002Vx board will also measure the in-series resistance created by the protections in place and the board itself. The user has to take this into account. On the right part of the dialog box (see Figure 12), the user can see the lead off detection and this impedance. The lead off is a continuous check of the positioning of the electrode placement on the body: when the relative flag becomes red, the user has to check the physical link on the patient.

Figure 12: Plot window of ECG data



Conclusions

This paper presents STMicroelectronics' new design useful for PoC. It represents the last result of the Analog Front End devices in the field of Electrocardiography.

Its modularity and its set of firmware and software permit the user to easily start from this project to design his own device.

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