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Long-Term Continuous Ambulatory ECG Monitor with Beat-to-Beat Heart Rate Measurement in Real Time using ESP32

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***Abstract*—This work presents a long-term continuous ambulatory ECG monitor for simultaneous acquisition and storage of leads DI, aVF, and V2, and beat-to-beat R wave detection using wavelet transform for heart rate measurement in real-time. The monitor has as its core the low-power ADS1294 analogue front-end of 4 channels, 24-bit analog-to-digital converters and programmable gain amplifiers, the low-power dual-core ESP32 microcontroller, a 32 GB micro SD memory for data storage and a 1.4 in thin-film transistor liquid crystal display (LCD) variant with a resolution of 128 x 128 pixels. The monitor has sampling rates of 1000 Hz, 500 Hz, and 250 Hz, bandwidth from 0 Hz to half the selected sampling rate, a CMRR of –115 dB, a resolution of 286 nV, a current consumption of 50 mA for an average battery life of 84 h, a lead-off detection and a real-time beat-to-beat heart rate measurement.**

Keywords—Long-Term Ambulatory ECG monitor, Heart Rate, ESP32, ADS1294, micro SD memory

I. Introduction

Long-Term Continuous Ambulatory ECG is a noninvasive test widely used in clinic to evaluate dynamic and transient electrocardiographic abnormalities of patients in various cardiac diseases providing a continuous recording of ECG data for 24 to 48 hours permitting the patients perform their normal activities [1][2].
The main clinical uses of the long-term ECG are: the diagnostic and assessment of cardiac symptoms, the prognostic assessment or risk stratification of cardiac disease populations and the evaluation of therapeutic interventions [2].

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The use of long-term ambulatory recordings for risk stratification of cardiac patients populations has permitted to evaluate RR interval variations between consecutive beats for the measurement and analysis of parameters with predictive value as the heart rate variability (HRV) [3] and the heart rate turbulence (HRT) [4].

Recently, new technology has allowed that ambulatory ECG monitors record for more than 48 hours [5], have more memory, lower power consumption, and are smaller and lighter weight. With the advancement of technological development, devices for long-term ECG acquisition have evolved from weighing 38 kg in its beginnings to weighing less than 0.5 kg. Currently, the designs have also improved in terms of storage capacity, resolution, sampling frequency, and the signal acquisition period has been extended, among other parameters [6], [7], [8].

In [9] and [10], we proposed two prototypes of long-term ambulatory ECG monitors with beat-to beat QRS complex detection in real time based on FPGA. In this work, we present an improved long-term continuous ambulatory ECG monitor for the measurement and analysis of the HRV and HRT using the low-power devices: ADS1294 analogue front-end and the dual core ESP32 microcontroller. This ambulatory ECG monitor has 3 selectable sampling rates and it allows simultaneous acquisition and storage of 3 leads, beat-to-beat heart rate measurement in real-time and lead-off detection for continuous periods until of 84 h.

II. Materials and Methods

The monitor proposed in this work has as its core an ADS1294, an ESP32 microcontroller, an LCD screen, a microSD memory (Fig. 1) and the low-consumption voltage regulator MCP1702T-33 [11] with an output voltage of 3.3 V.

To develop the firmware implemented in the ESP32, the Arduino 1.8.2 software was used, to which the specific libraries for the device were added.

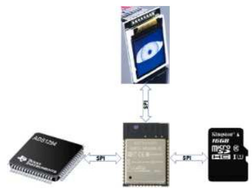

Fig. 1. Main components of the long-term continuos ambulatory ECG monitor of 3 leads with R wave detection in real time.

A. ADS1294

Texas Instrument's ADS1294 is a family of multidirectional, simultaneously sampling, delta-sigma (ΔΣ) analog-to-digital converters (ADCs) with 24-bit resolution, amplifiers with programmable amplification factor, internal reference, and a built-in oscillator. The ADS1294 incorporates all the features that are required in electrocardiographic applications with high levels of integration and exceptional performance [12]. Among the options that the monitor uses are the lead-off detection to verify that electrodes are properly connected, the Wilson central terminal and the Goldberger central terminal. The ADS1294 also manages the digitization of each one of the ECG leads.

B. MicroSD memory

The microSD card used in the design is a Kingston brand microSDHC Class 10 with a capacity of 32 GB that reaches reading speeds of 45 MB/s and 10 MB/s writing; although 4 GB, 8 GB, 16 GB and 32 GB memories can be used in the device if they are Class 4 or higher. The technical specifications of the microSD memories allow them to be used in working and storage temperatures ranging from -40°C to +85°C, with a relative humidity of 95%. Kingston's microSDHC memory card can be removed and/or inserted without powering off the host system, but it does not have a mechanical write-protect switch [13]. In the monitor, the microSD memory is used to store the data obtained by the ADS1294.

C. ESP32 Microcontroller

The ESP32 is a series of low-cost, low-power microcontrollers with integrated Wi-Fi and Bluetooth technology designed for mobile and Internet of Things applications. The ESP32 contains a single or dual core Xtensa 32-bit LX6 Microprocessor, capable of performing up to 600 Million Instructions Per Second or MIPS (200 MIPS for ESP32-S0WD, 400 MIPS for ESP32-D2WD). It has a program memory capacity of 448 KB ROM, a 520 KB SRAM memory, a 16 KB SRAM memory in the RTC and allows the addition of multiple external flash/SRAM memory chips. This device allows different ways to generate its operating clock by means of an internal 8 MHz oscillator with calibration, an internal RC oscillator with calibration or an external crystal oscillator from 2 MHz to 60 MHz can be added [14].

The ESP32 microcontroller programmed in C language, implements the communication interfaces with the ADS1294 integrated circuit, the microSD memory and the LCD screen. In addition, it implements the algorithm based on the continuous wavelet transform (CWT) for the beat-to-beat detection of the QRS complex for the heart rate measurement in real-time [15].

The developed algorithm uses *B*-splines as basic functions, which allow the evaluation of the CWT at any integer scale, so that the ECG can be analyzed at a wide range of scales and to reduce noise and artefacts. As the wavelet function used is the first derivate of a cubic B-spline of 4^{th} order expanded by two, the QRS complex corresponds to a pair of modules: positive maximum-negative minimum (PN_{mm}) of the CWT in different scales, where the rising slope represents to a negative minimum and the falling slope represents a positive maximum. Then, the R wave peak corresponds to the zero crossing point between the pair of modules PNmm [15][16]. This algorithm produces a maximum delay of 50 ms in the R wave peak detection, which may decrease depending on the morphology of the QRS complex.

D. LCD display

The screen used is a variant of liquid crystal display (LCD) that uses thin film transistor (TFT) technology to improve its quality. This screen is controlled through the SPI communication protocol, has a diagonal measurement of 1.4 in, a supply voltage that can vary in the range of 3.3 V to 5 V, and a white LED for the backlight that can be controlled with a PWM channel. This screen has a resolution of 128 x 128 pixels, with a TFT controller (ST7735 [17]) that can display 16 full colors. In the monitor, the LCD liquid crystal screen facilitates the user's interaction with the system, allows the configuration of the device and the visualization of the electrodes connection, the heart rate and the ECG.

E. Software implemented in the ESP32

The designed device has a visual interface that is displayed on the LCD screen. The visual interface is composed of 8 screens each with different functions (Fig.2):

1. Start: Device Settings.
2. Error: Shows if a malfunction occurs.
3. Main: Central menu of the monitor.
4. Configuration: Modify the prototype parameters.
5. Memory: Shows information of the connected memory.
6. Date-Time: Allows you to modify the date and time.
7. Patient data: Enter the data of the subject of the registry.
8. Record: Shows the ECG information.

Of the screens shown in Fig. 2, the most important are Configuration and Record. In the Configuration screen it is possible to control the brightness of the device screen, define the sampling frequency of the device that can be 250 Hz, 500 Hz or 1000 Hz, enable the detection of faults in the electrodes connection and set the duration that the LCD remains on after a period of inactivity.

In the Record screen it is possible to see the heart rate in real time in the FC parameter of the plotted lead calculated with the algorithm developed in [10],[14]. Know the electrode status through the parameters RL, LL, LA, RA and V2; if the circle is green, there are no faults and if it is red, there are faults in the electrode. It is also possible to select between the three leads DI, aVF and V2, which one will be plotted.

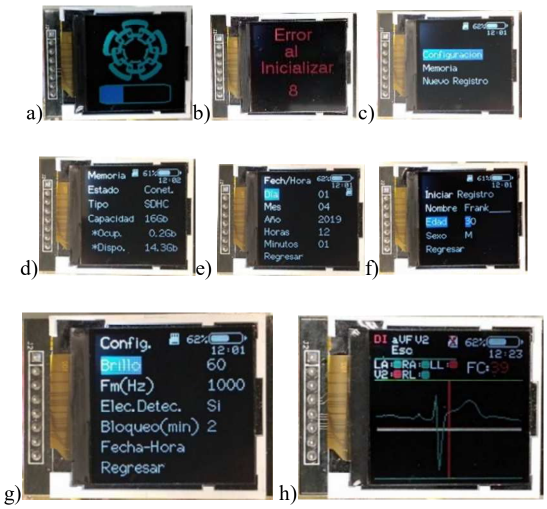

Fig. 2. Display screens. a) Start. b) Error. c) Main. d) Memory. e) Date-Time. f) Patient data. g) Configuration. h) Record.

To interact with the visual interface, the device has 5 buttons that allow you to scroll through the menus, select and modify parameters. In addition, if the device is not performing any activity after a time, it goes into low consumption mode, and if the device is acquiring a signal after a time without activating any button, the screen turns off to minimize energy consumption.

In each of the screens, except for the startup and error screens, it is possible to know the status of the battery, the system time, and the status of the microSD memory (whether it is connected or not). To store the records obtained in the microSD memory, the device creates a folder in the base directory of the microSD memory with a name in the format shown in Fig. 3.

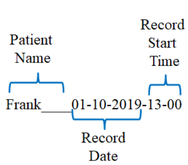

Fig. 3. Format of the name of the directory where the logs are stored.

The name of this folder is made up of the Patient's name, the date, and the time that the system has when the registration starts. The files containing the information obtained from the ADS1294 and the QRS complex detection of each of the leads (DI, aVF, V2) are stored within this folder. These files are named as Record0000, Record0001, …, Record9998, Record9999. The file Record0000 stores the patient data collected on the Patient Data screen, and the rest of the files store the results of the digitization and the data obtained from the QRS complex detection.

F. Monitor printed circuit design

Initially the prototype was designed in a very rustic way composed of 5 independent circuit boards stacked one on top of the other. Once the correct functioning of the monitor was verified and the programming of the ESP32 microcontroller was validated, a second stage was passed to start the optimization of the monitor, with a greater emphasis on size reduction, but separating the digital signals from the analog signals to minimize high-frequency noise in the ECG. The newly developed version concentrates all the components on a single board with approximate dimensions of 36.3 mm by 66.4 mm as shown in Fig. 4.

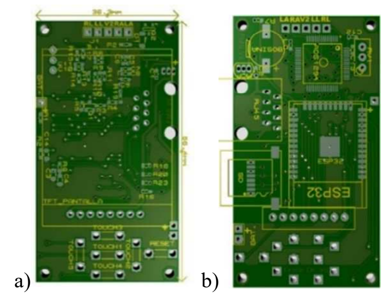

Fig. 4. Printed circuit board. a) Upper face. b) Lower face.

In the design, the upper face of the board has the LCD screen and the buttons, fundamental elements for the user's interaction with the system. On the underside of the board there is the ESP32, the microSD memory and the ADS1294, elements responsible for the acquisition, processing, and storage of ECG signals. For the connections of the device with the outside, a DB-15 connector was used; the connector is used for battery charging, device programming, and connecting the electrodes needed to acquire the ECG signal.

This design has the advantage that the ADS1294 can be replaced without major modification by the ADS1296 or ADS1298 to increase the number of ECG leads; or change the ADS1294 by the ADS1299 for EMG or EEG use. It also allows to implement a Bluetooth and/or Wi-Fi transmission for connection to a cell phone or a server.

G. Monitor Case Design

For the design of the box, the Autodesk Inventor 2022 application was used, this software allows the design of parts in 3 dimensions with precision and generates the necessary files for 3D printing. A combination of metal inserts for M2 screws and PLA plastic was used in the construction. With the Autodesk Inventor 2022 application, several prototypes were designed until reaching the final version shown in Fig. 5.

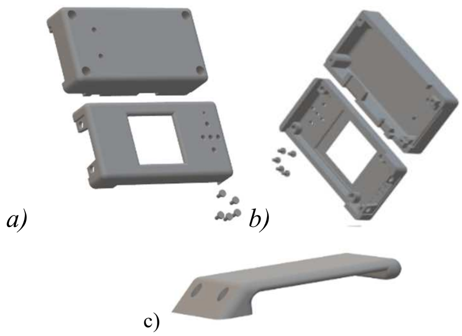

Fig. 5. Monitor case design. a) Upper face. b) Lower face. c)Fastening tab.

III. Results and Discussion

In Fig. 6, the final version of the assembled monitor is shown, which has dimensions of 84.1 x 43.0 x 29.8 mm without the fastening tab or 84.1 x 43.0 x 38.8 mm if the tab is included and has a weight of approximately 129 g.

Fig. 6. Final monitor.

A. *Validation of acquisition of the ambulatory ECG monitor*

To verify the acquisition of the developed ambulatory ECG monitor, two tests were performed: the first was connected to the METRON PS-420 simulator of the manufacturer FLUKE to validate the gain of the device, the detection of the heart rate in real time and the detection of the electrodes connectivity. In the second test, a comparison was made with the BIOPAC MP36 system and its LABEL SS2LB ECG module [18]. This device has the CE marking of the European Union for medical devices. In this test, a simultaneous acquisition of the ECG signal was performed; with both devices connected to the same electrodes of a test subject. For the signal acquired by the BIOPAC MP36, a gain of 5 and a bandwidth of 0.05 Hz to 150 Hz were established.

The two acquisitions obtained from the ECG (Fig. 7) were analyzed with the algorithm developed to detect the QRS complex [16], and measure the RR intervals to obtain the tachogram shown in Fig. 8a.

Fig. 7 shows that the morphology and amplitude of the two signals are very similar. To validate this assumption, the signals were synchronized, and the correlation was calculated in the first 5 min of the two records, obtaining a value of 91.78%.

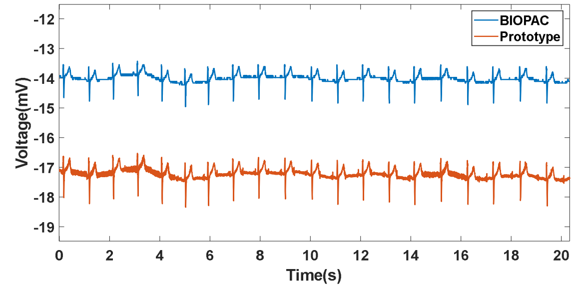

Fig. 7. Comparison of the records taken by the BIOPAC and the monitor at a sampling frequency of 1000 Hz and without input filters.

In Fig. 8a, the tachograms of the two signals were compared, which allows us to validate two elements, the first element, that the developed algorithm can detect the location of the R wave peak when there are small variations in the signal. The second element is the verification of the sample rate on the device. To evaluate the measurement of the RR intervals in the simultaneous recordings acquired by the two devices and compare their variability, the Bland-Altman statistical method [19] (Fig. 8b) is used, establishing the confidence interval as ± 1.96*SD of the measured difference (in this work the SD = ± 2.83 ms and the mean difference is approximately 1.00 ms).

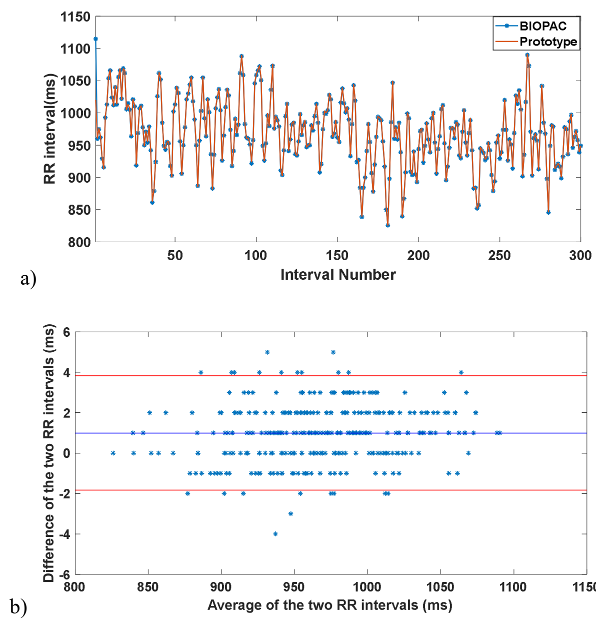

Fig. 8. Validation of the performance of the designed monitor. a). Tachogram b). Bland–Altman plot

B. *Device Parameter Validation*

In the device it is necessary to identify certain characteristics that define the quality of the acquired signal:

- CMRR calculation
- Bandwidth
- Entry margin
- Resolution

- Calculation of the minimum memory capacity required to store a 24-hour record.

For the CMRR, Bandwidth, Resolution and Input Margin parameters, those calculated by the manufacturer were used since no additional component was connected to the ADS1294. The CMRR is –115 dB as stated in the ADS1294 specifications. The bandwidth is defined from 0 to half the sampling frequency, as the developed device can take values of 250 Hz, 500 Hz and 1000 Hz (0 Hz to 125 Hz, 0 Hz to 250 Hz, 0 Hz to 500 Hz). For the input margin, there is ±2.4 V for the unity gain, but if necessary in the future, the gain can be increased, which would reduce the input margin. In the calculation of the resolution, the 24 available bits of the ADS1294 and the input margin of ±2.4 V were used; obtaining 286.10 nV (Eq. 1) [12]:

$$\text{Resolution}_{adc} = \frac{V_{ref}}{2^{n}-1} = \frac{2*2.4\ V}{2^{24}-1} \approx 286.10\ nV \quad (1)$$

For the calculation of the minimum storage capacity for a 24-hour record, 5 bytes are needed for each channel (3 bytes for the channel sample and 2 bytes for the calculated heart rate). Therefore, 15 bytes are needed each time an acquisition is performed since 3 channels are being monitored simultaneously (DI, aVF, V2). For the calculation, a sampling frequency of 1000 Hz will be taken as it is the maximum that the designed monitor admits (Eq. 2).

$$\text{Storage}_{min} = 15\,\frac{bytes}{\text{samples}} * 1000\,\frac{\text{samples}}{s} * 1\ \text{day}$$
$$= 1\,296\,000\,000\ bytes = 1.21\ GB \quad (2)$$

Since the monitor can store up to approximately 84 hours, a memory of more than 4.26 GB is recommended. The designed prototype can identify memories of 4 GB, 8 GB, 16 GB and 32 GB; but it is necessary that they be class 4 or higher because the speed of writing to memory is a critical element so that the storage buffers of the ESP32 are not saturated.

C. Power consumption and battery life

To perform a theoretical calculation of the maximum duration of the battery, the maximum current consumed by the monitor was obtained. Obtaining the maximum current of the device was measured when recording was acquired with a frequency of 1000 Hz, the screen permanently on, electrode detection activated and writing to the microSD memory.

Under these conditions, the device has a maximum consumption of 50 mA at a regulated supply voltage of 3.3 V (Note this consumption is not constant and most of the time it is less), which is equivalent to a maximum consumption of 165 mW. In the prototype, a 103665 Seamuing brand rechargeable Lithium 3.7 V 3000 mAh battery was used, which provides an ideal power of 11100 mWh. With the battery used, it has a theoretical duration of 67.27 h, but in practice, the device does not have that performance. Since it is only possible with an ideal transfer of energy and with a constant consumption of 50 mA, but in the device that consumption only occurs when all the elements are active.

To validate the real life of the battery, a life test was carried out under the conditions mentioned above and the battery charged to 100% was recorded until the device was turned off. This method was repeated 5 times and the result averaged, achieving a device performance of approximately 84 h, exceeding the minimum 24 h continuous operation requirement.

D. Comparison with previous works

Currently, the performance of ambulatory ECG monitors continues to be optimized by improving resolution, recording duration, size and weight. In the new monitors we are adding the ability to connect to the cloud via wireless connection [19][20][21], in this monitor will be added in the future taking advantage of the capabilities of ESP32 to implement a Bluetooth connection and Wi-Fi.

The monitor developed is the continuation of those shown in the ambulatory ECG monitors [9][10], in order to improve their performance. The first characteristic to note was the platform change from FPGA to a microcontroller. This change has the disadvantages that the parallel processing capacity present in the FPGA is lost, but that is compensated by the ESP32 characteristic of having two cores, which allows two lines of work, and the other disadvantage is the rigidity of the ESP32 of having the preset peripherals. The benefits of platform change are lower power consumption and faster application development.

In this monitor, several parameters were improved as shown in Table I with respect to [10], for example, the volume decreased by 403%, the weight decreased by 329.2%, the consumption decreased by 257.6% and the duration of the battery increase 233% with a 3000 mAh battery.

TABLE I. COMPARISON OF THE CHARACTERISTICS OF THE DEVELOPED PROTOTYPES AND COMMERCIAL HOLTER.

Parameter	**This work**	J. A. Garcia-Limon et al. [10]	Cardioline Clickholter [22]
Sampling frequency	1000 Hz, 500 Hz, 250 Hz	1000 Hz	500 Hz, 250 Hz
Dimensions (mm)	29.8x43x 84.1	55.40x77x102	20x65x96
Volume (cm3)	107.8	435.1	124.8
Weight (g)	129.1	425	90
Power consumption (mW/h)	165	425	--
Battery duration (h)	84	36	48
Resolution (nV)	286	761	< 1000
Measurement range (mV)	4800	49.9	800

If the new prototype is compared with the commercial device [22] the parameters are very similar; in the prototype is 15% smaller, but the commercial device is 43% lighter and the battery life is 75% longer in the prototype, but the commercial device can exchange batteries.

In addition, the way of storing the information was improved to facilitate subsequent processing. The user interface was updated, allowing the time and memory status to be always known. It is also possible to view one of the digitized leads, the heart rate, and the status of the electrodes in real time.

IV. Conclusions

In this work, a prototype of a long-term ambulatory ECG monitor was developed for the simultaneous acquisition of leads DI, aVF and V2 of the ECG. The designed device is light weighing 129 g, compact with dimensions of 84.1 x 43.0 x 38.8 mm, it has a CMRR of –115 dB, resolution of 286.10 nV, input margin of ±2.4 V and it allows to select between different frequencies of sampling 250 Hz, 500 Hz and 1000 Hz. In addition, it detects the connection status of the electrodes, it digitizes and stores ECG records, and it calculates the heart rate in real time from three simultaneous leads for periods longer than 80 h continuously; as long as the microSD memory capacity allows it (4 GB, 8 GB, 16 GB and 32 GB).

Compared to a commercial device, the main advantages are that the prototype detects real-time beat-to-beat heart rate of all three leads and stores them, and it has a higher sampling rate and higher resolution. This allows to obtain long-term records of 84 h with high quality, facilitating the analysis of the HRV and HRT. As future work, we will optimize the design and energy consumption of the prototype, adding the ability to send alarms via Bluetooth to a cell phone when arrhythmias occur in real time and the implementation of software on a PC to analyze the records obtained.

The monitor will be used in clinic to create a database of long-term ECG recordings of diabetic patients with the aim of evaluating their risk of cardiovascular disease through indices based on HRV, HRT and ventricular repolarization intervals.

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