6th International Electronic Conference on Sensors and Applications
ECSA-6

“Portable ECG system design using the AD8232 microchip and open-source platform”

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15/Nov/2019

CONTENTS

PROBLEM STATEMENT

- ✓ Cardiovascular diseases (CVD) are one of the leading causes of death worldwide. World Health Organization (WHO) reports indicate that 31% of deaths are due to CVD.
- ✓ In the last decades there has been an alarming increase in the population that presents cardiovascular problems, being one of the main causes of death worldwide, which due to lack of knowledge or identification of the problem tend to end up in death due to heart attack or heart conditions [1].
- ✓ A trend that helps to address this problem is the development of medical devices for personal use, known as “mobile health”, with the use of technology such as: smartphones, monitoring sensors, and software applications that register , transmit or store user data to access their health condition at all times [2].
- ✓ Mobile health wearables market is extremely fast-moving, and consumers demand more accurate battery-powered mobile devices.

Figure 1. Mobile Health Scheme.

JUSTIFICATION

Figure 2. Current Mobile Health Systems.

- This project proposes the development of an ECG system with the AD8232 chip for long time recording and real-time ECG monitoring (online) in a low cost system based on an open source platform.

The proposed prototype offers the following advantages:

- ✓ Long time ECG recordings
- ✓ Real-time transmission on smart devices
- ✓ ECG records with .txt format for easy information management.
- ✓ 3 communication protocols for connectivity with smart devices

- The portable monitoring equipment allows to register the vital signs while the user performs his daily activities, and to capture events that occur infrequently or specific circumstances, and thus be able to make a more precise diagnosis.

BACKGOUND

Electrocardiograph portability

- ✓ Norman Holter in 1949 - backpack, about 37 Kg, with ECG registration and transmission.

Figure 3. First portable electrocardiograph.

- ✓ Currently portable devices, "mobile health" for personal monitoring and health care.

Figure 4. Mobile Health Scheme.

- ✓ The need to develop miniature equipment is considered by semiconductor companies that develop microchips.

Semiconductor companies

- IMEC
- Texas Instruments
- Analog Devices

(Developing microchips for the development of miniature and "wearable" equipment)

Figure 5. Semiconductor companies.

BACKGOUND - RELATED WORK

Table 1. Current mHealth single channel ECG devices.

Modelo	CMRR	Bandwith (Hz)	Sampling frequency	Recording duration	Cost (USD)	Data display	Data storage
Iwatch apple [3].	NA	NA	NA	30 s	499-699	IPhone, Ipad.	Memoria dispositivo
Alivecor, Kardia [4].	76dB	0.5-40	300 Hz	30 s	249	Smartphone	Memoria dispositivo
Qardiocore [5].	NA	0.05-40	600 Hz.	24h	500	Smartphone	Memoria dispositivo.
ECG Anywhere [6].	≥105	NA	500 Hz.	NA	400	Tablet, Smartphone	Memoria dispositivo
Spyder wireless ECG [7]	>100	0.5-25	125 Hz	72 h	500	Smartphone	Nube internet
CardioSecur [8]	NA	0.5-40	250-500 Hz.	30 m	130 +120 subscription.	LCD Screen and software PC	microSD card

Table 2. Documents related to application of the AD8232 chip in mHealth portable systems.

Reference	Document type	Year	Description
Un electrocardiógrafo inteligente de bajo coste [9].	Thesis	2014	AD8232 chip and Arduino for portable ECG application.
Wireless Hybrid Bio-Sensing with Mobile based Monitoring System [10].	Thesis	2013	AD8232 chip and Arduino for portable ECG application.
A Health Shirt with ECG Real-time Display on Android Platform [11].	Article	2014	AD8232 chip and Arduino for portable ECG application.
A Portable ECG Monitor with Low Power Consumption and Small Size Based on AD8232 Chip [12].	Article	2014	AD8232 chip and Arduino for portable ECG application.
Design of ECG Homecare:12-Lead ECG Acquisition using Single Channel ECG Device Developed on AD8232 Analog Front End [13].	Article	2015	AD8232 chip and Arduino for portable ECG application.
Designing a low-cost real-time group heart rate monitoring system [14].	Article	2018	AD8232 chip and Arduino for portable ECG application.
Simple fabrication method of an ultrasensitive gold microstructured dry skin sensor for biopotential recording [15].	Article	2018	Dry microelectrode development, with the AD8232 chip and Arduino.
A wearable H-shirt for exercise ECG monitoring and individual lactate threshold computing [16].	Article	2017	ECG T-shirt for exercise with AD8232 chip, App interface on Smartphone with classification algorithms.

BACKGOUND - AFES (Analog Front End) microchips

- ✓ Advances in the area of microelectronics have allowed the development of multifunction integrated circuits for the acquisition of biopotentials, developed by companies: IMEC, Texas Instruments, *Maxim Integrated* y Analog Devices, enabling the development of portable medical instruments and wearables [17-19].
- ✓ These new specialized integrated circuits, known as AFE ("Analog Front-End") are aimed at conditioning biosignals for digital stethoscope, electrocardiogram (ECG), electromyography (EMG), pulse oximeter (SpO2) and bioimpedance.
- ✓ Reduce component cost by over 50% of a discrete design , a single-chip solution increases system reliability and patient mobility
- ✓ Reduce components and board size by 80% and also reduce noise pick-up, have low energy consumption allowing the development of long-life portable equipment and lightweight [21, 22].
- ✓ Since 2011, Analog Devices and Texas Instruments companies introduced AFE integrated circuits for ECG application [20].
- ✓ In 2012, the Analog Devices AD8232 microchip won the award for best electronic design of AFE single-lead heart-rate monitor, in the category of medical innovation [21].

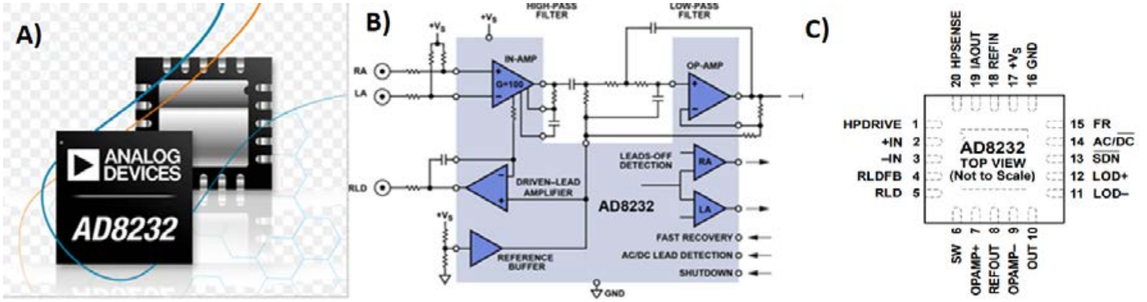


Figure 6. A) Microchip AFE AD8232. B) Diagram of the internal structure of the AD8232 microchip. C) AD8232 microchip footprint .

PROJECT OBJECTIVES

General Objetive:

Manufacture a prototype of a portable ECG system with data logging and wireless data transmission, using the AD8232 chip as an initial analog stage, and open source development platform.

Specific Objetives:

- ✓ Evaluate and validate the operation, scope and limitations of the AD8232 microchip, for monitoring the ECG signal.
- ✓ Characterize the Arduino open source platform with C programming, to increase its performance in the application of a data acquisition system and application of digital filters in real time.
- ✓ Design the circuit of a portable ECG system with the following modes of operation: serial transmission, microSD card recording, and Bluetooth transmission.

MATERIALS AND METHODS

Open-source hardware → Open-source software → AFE AD8232, adapter and simulation → Circuit implementation and testing → Data ouput modes → Buffer overrun problem

AD8232 CIRCUIT SIMULATION

Multisim simulation* Component development * Macromodel * Circuit design

Circuit Specs:

*Gain

*Cutoff frequencies

*Filters evaluation

System robustness:

*Montecarlo

*Temperature Analysis

*Worst Case

*Fourier Analysis

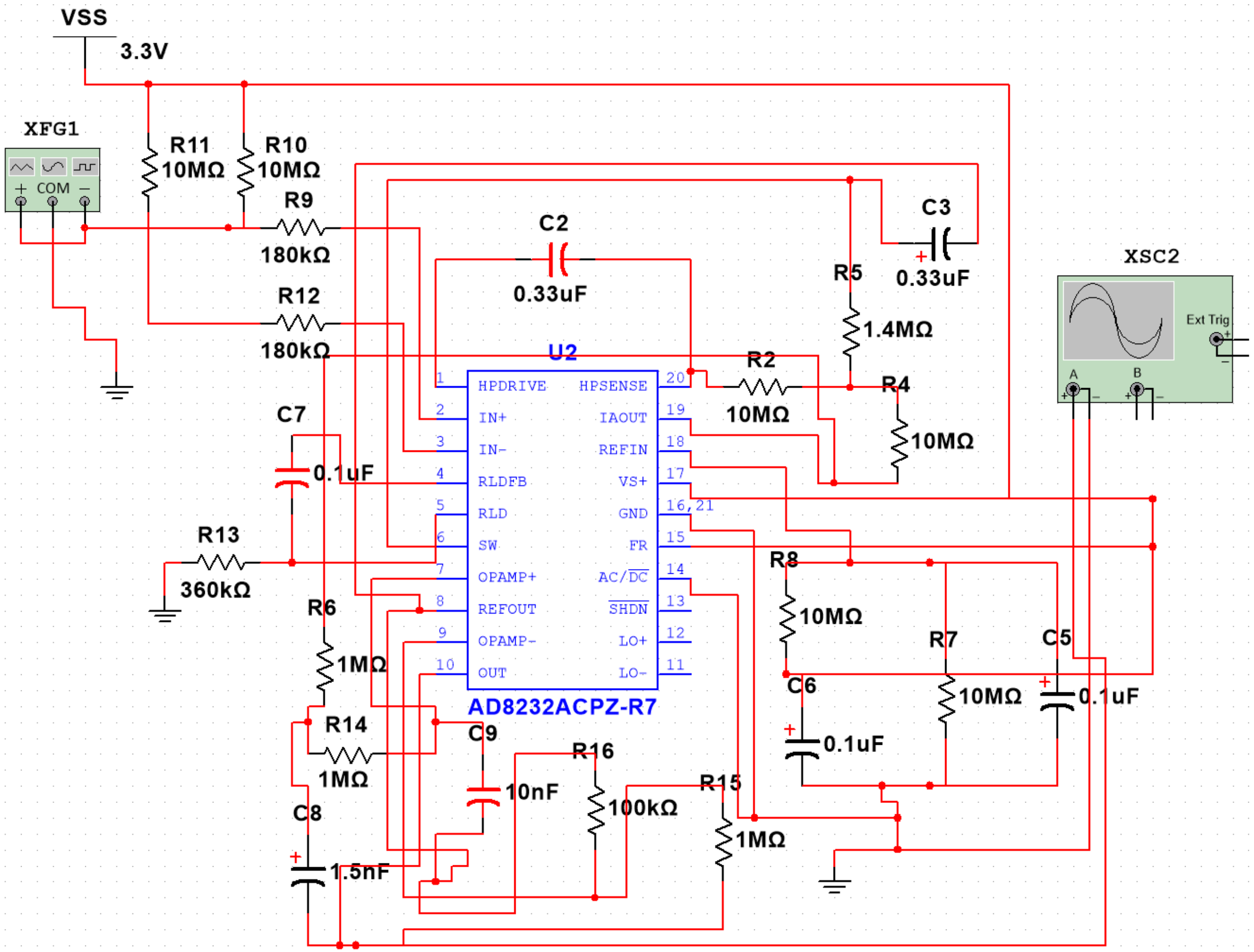
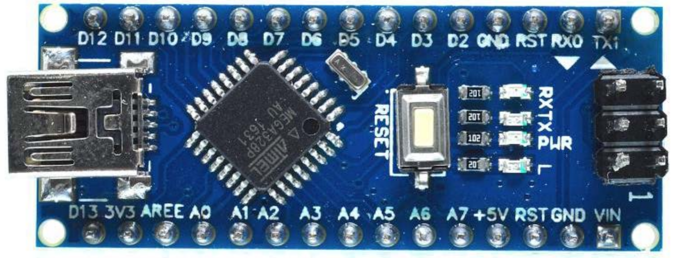


Figure 7. Circuit with SPICE component in Multisim software .

OPEN-SOURCE HARDWARE

Arduino Nano CH340

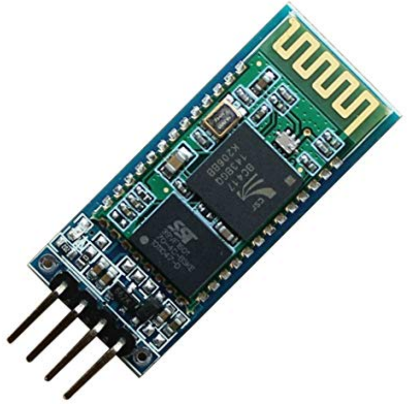


*ATmega328 Microcontroller

*16 MHz oscillator

*CH340 USB interface

Bluetooth HC-06

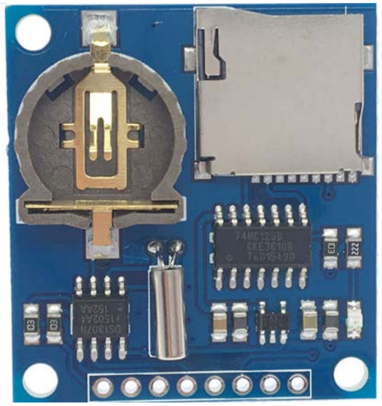


*AT commands

*Integrated antenna and RF transceivers

*115,200 bauds operation

Data Logger Shield



* RTC1307

*MicroSD reader

*Coin battery

*Level 5V to 3.3V regulator

Figure 8. Open-source boards and features.

OPEN-SOURCE HARDWARE

Open-source hardware is one whose design specifications and schematic diagrams are public access, either under some kind of payment or for free. The designation of open-source hardware refers to the freedom to use the device and its documentation in a design, but still you need to buy the integrated circuits.

Advantages:

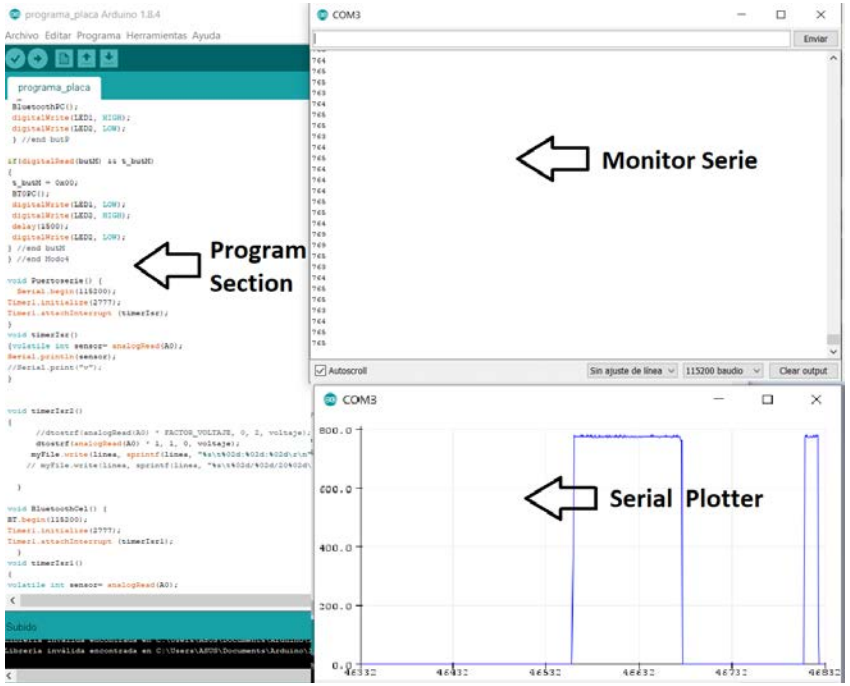
- Technological independence
- Promotes hardware quality and open standards.
- Collaborative work between designs allows their reuse and adaptation.
- Reduce costs and design times in projects.

Disadvantages:

- Designs are specific and unique.
- The availability of components is difficult in developing countries.
- Hardware manufacturing involves the design, simulation, production and implementation infrastructure.

OPEN-SOURCE SOFTWARE

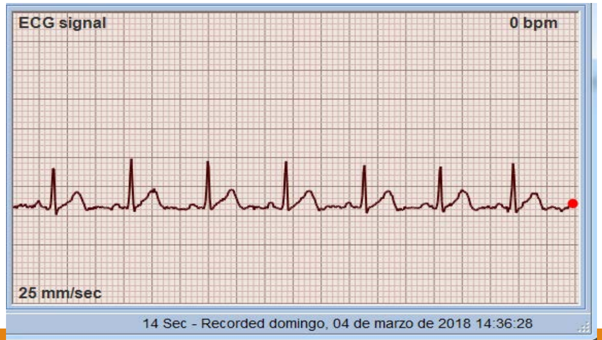
IDE Arduino



Arduino libraries

- Serial Communication: Use of UART port.
- SD Library: write the information to micro SD
- Timer One: Interrupt programming
- Software Serial: Virtual UART port configuration.

Theremino



Bluetooth Graphics

Figure 9. Open-source software and libraries.

OPEN-SOURCE SOFTWARE

Open-source software is one that can be distributed, modified, copied and used; therefore, it must be accompanied by the source code to make effective the adoptions that characterize it. It is convenient not to confuse open-source software with free software, this last one does not cost anything, a fact that does not turn it into open-source software, because it is not a question of price, but of freedom to abide by the agreement of use.

Advantages:

- Low cost of acquisition and freedom
- Technological innovation
- Lower hardware requirements
- Public support (software users)
- Supplier independence.

Disadvantages:

- It has no guarantee from the author.
- There is no responsibility for damages for use of the software.
- Instability in user interfaces (GUI).
- You must have knowledge of programming.
- When an error occurs you must use your own resource to solve it.

SOFTWARE-OPERATING MODES MENU

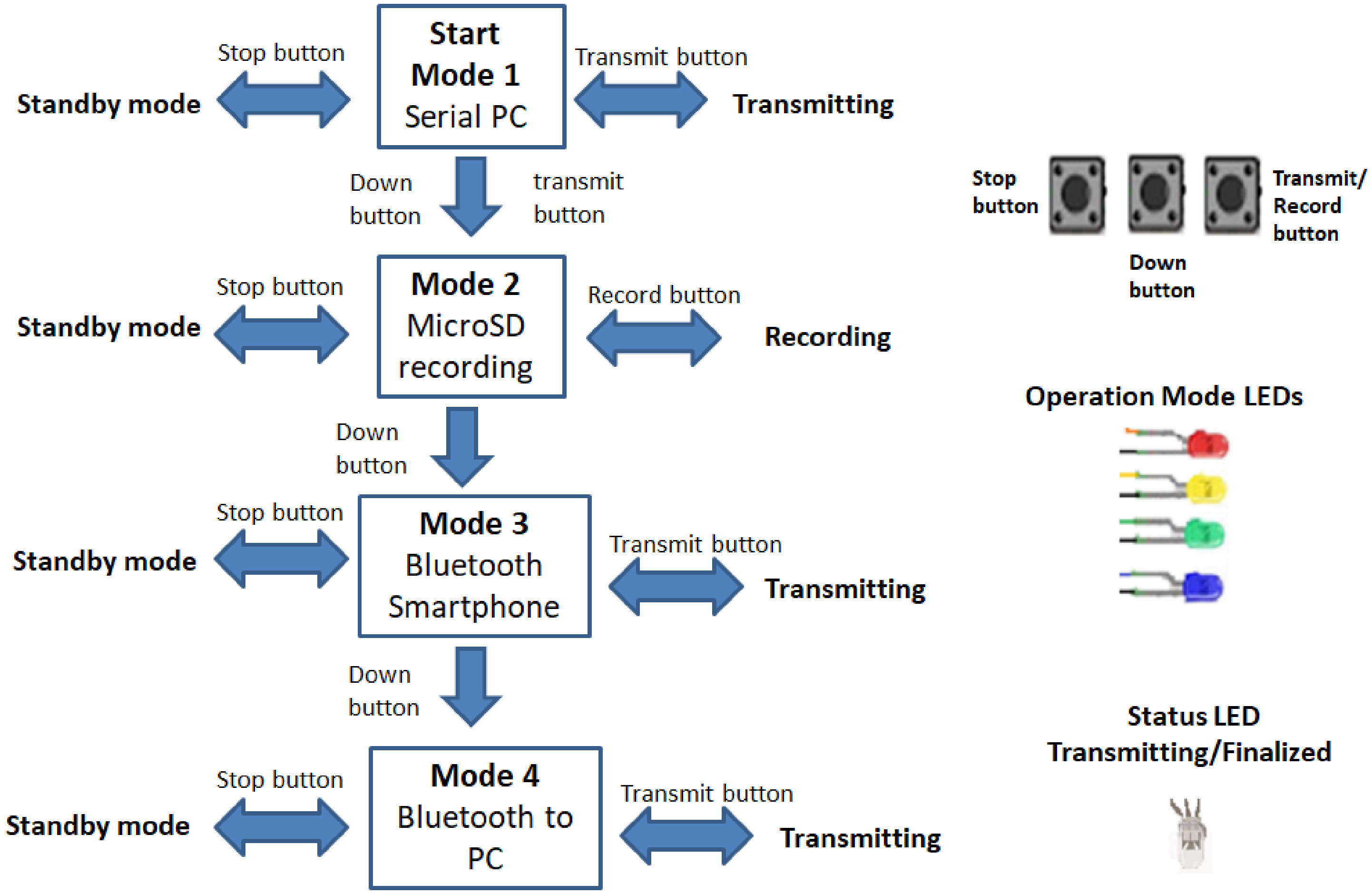


Figure 10. The operating menu of the portable ECG prototype is displayed. Pressing the down button will change the mode, and pressing transmit or record to start task, and the Stop button to end. The status LED will be green if it is being transmitted / recorded and it will be red if it is finished.

-SOFTWARE- DATA OUTPUT MODES

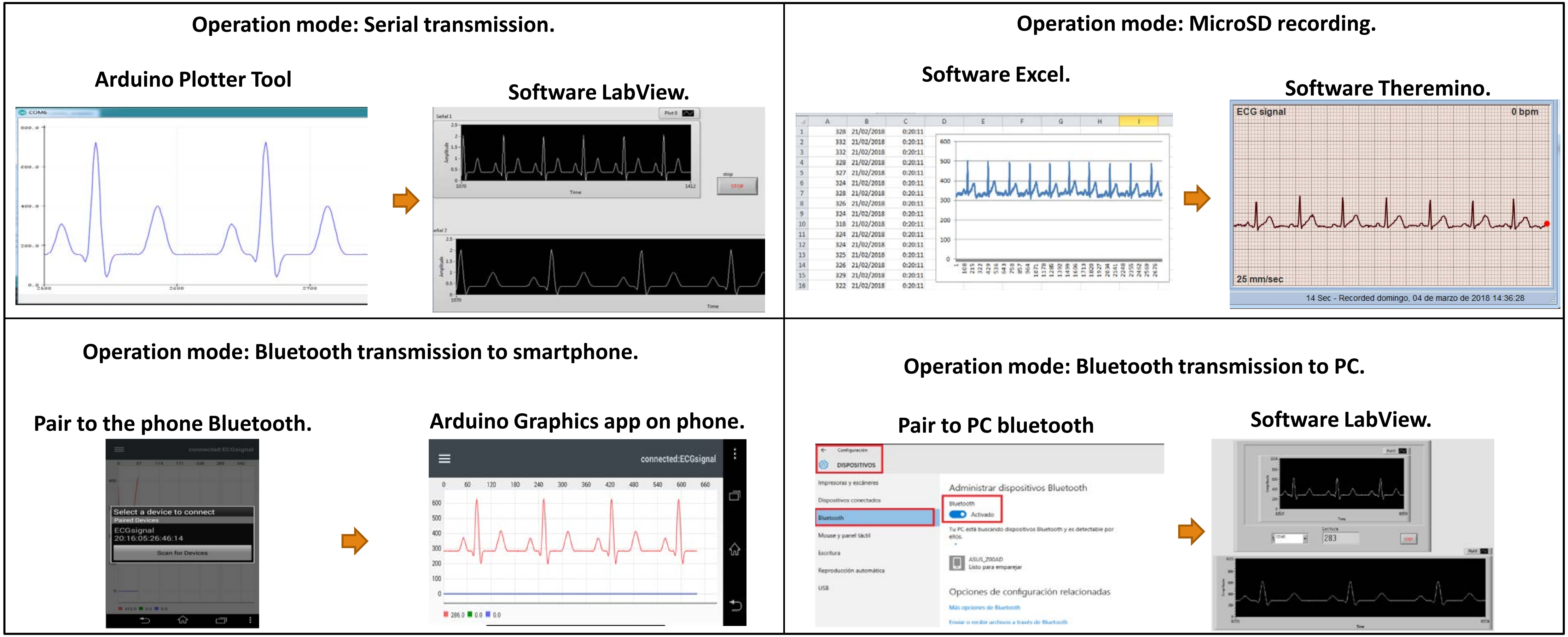


Figure 11. Data outputs modes.

INTEGRATED PROTOTYPE

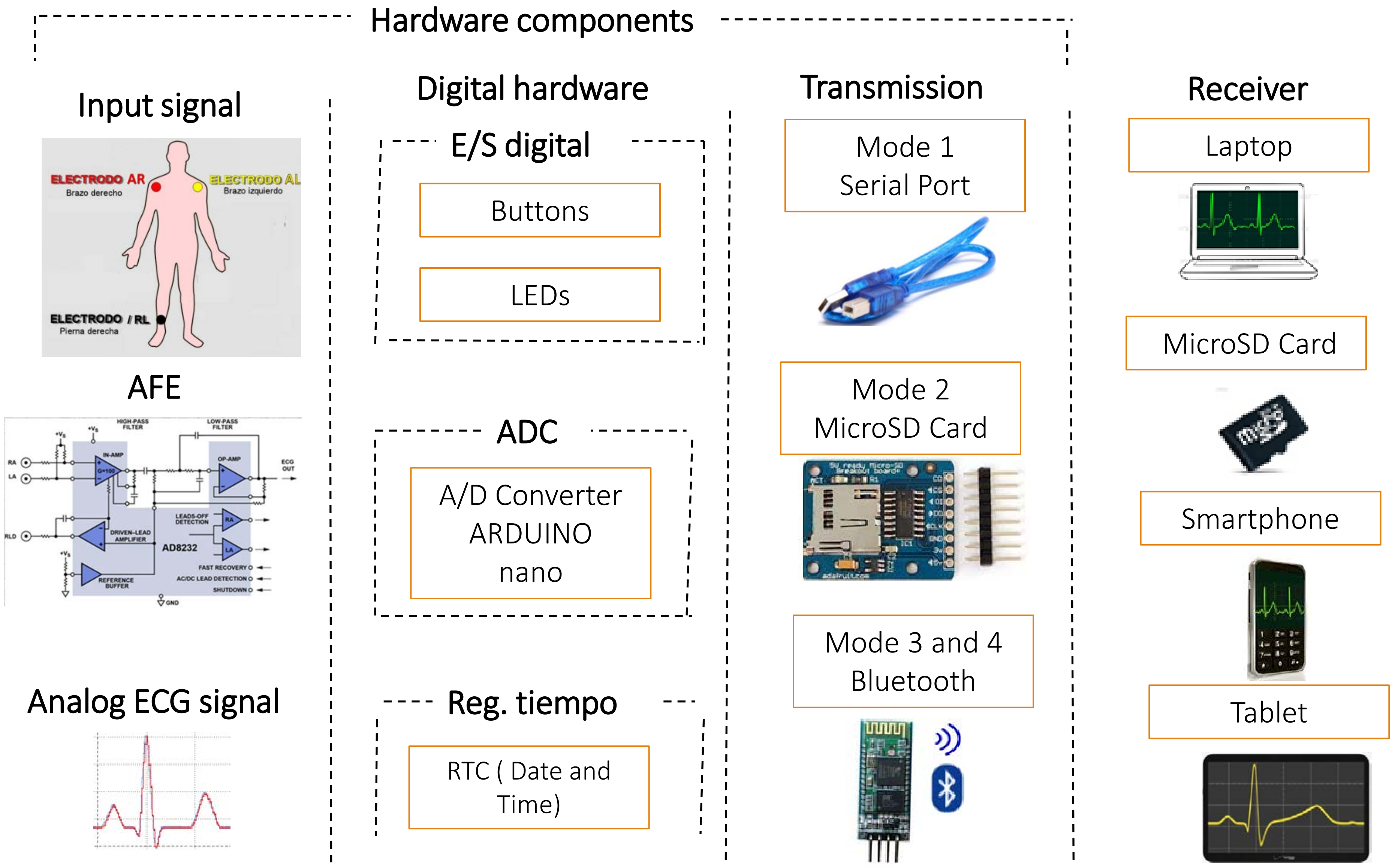


Figure 12. Integrated prototype.

Prototype connectivity

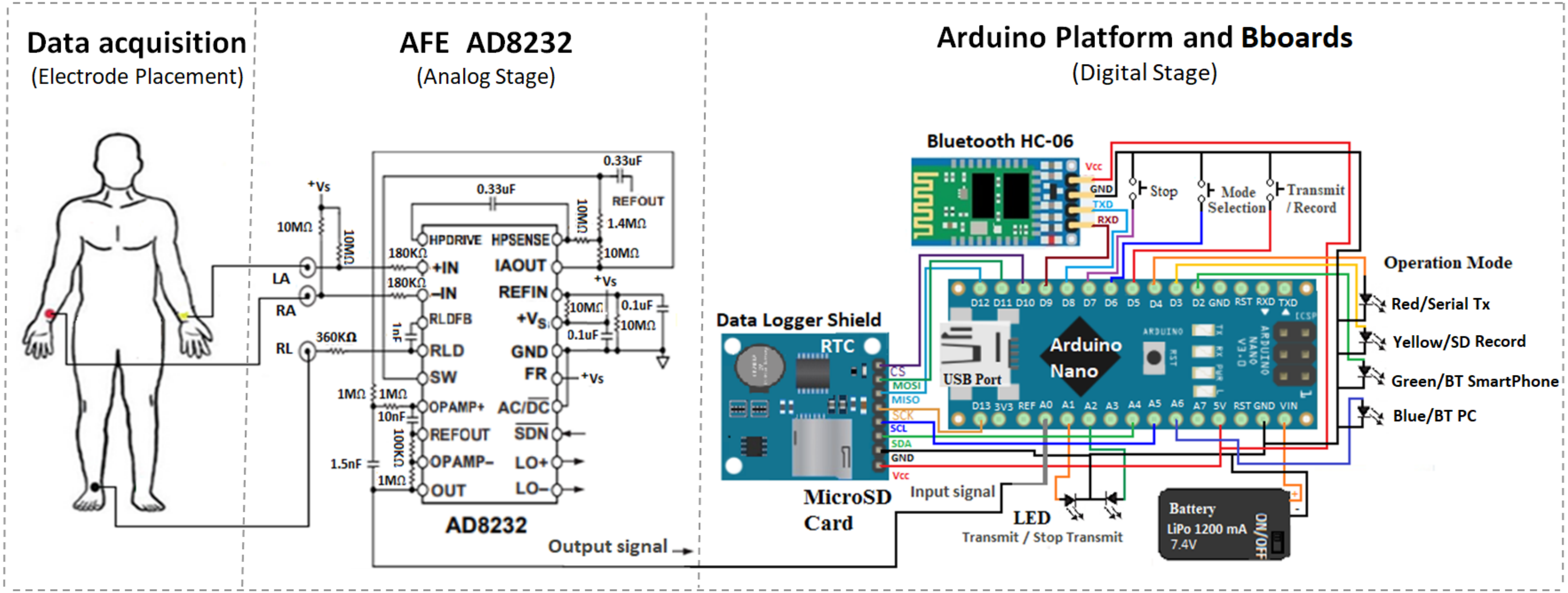
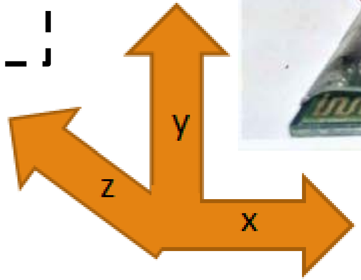


Figure 13. Prototype of portable ECG is shown. Circles on the person's body represent the position of electrodes. Two main sections: the analog AFE AD8232 and the Arduino modules.

Breadboard Prototype Specifications

- Breadboard 3M model 922309
  - Dimensions: **10.16x17.78cm**
  - 65 connection lines.
  - 840 points.
- Z-axis components on breadboard :
  - *Data logger shield*
  - Bluetooth module



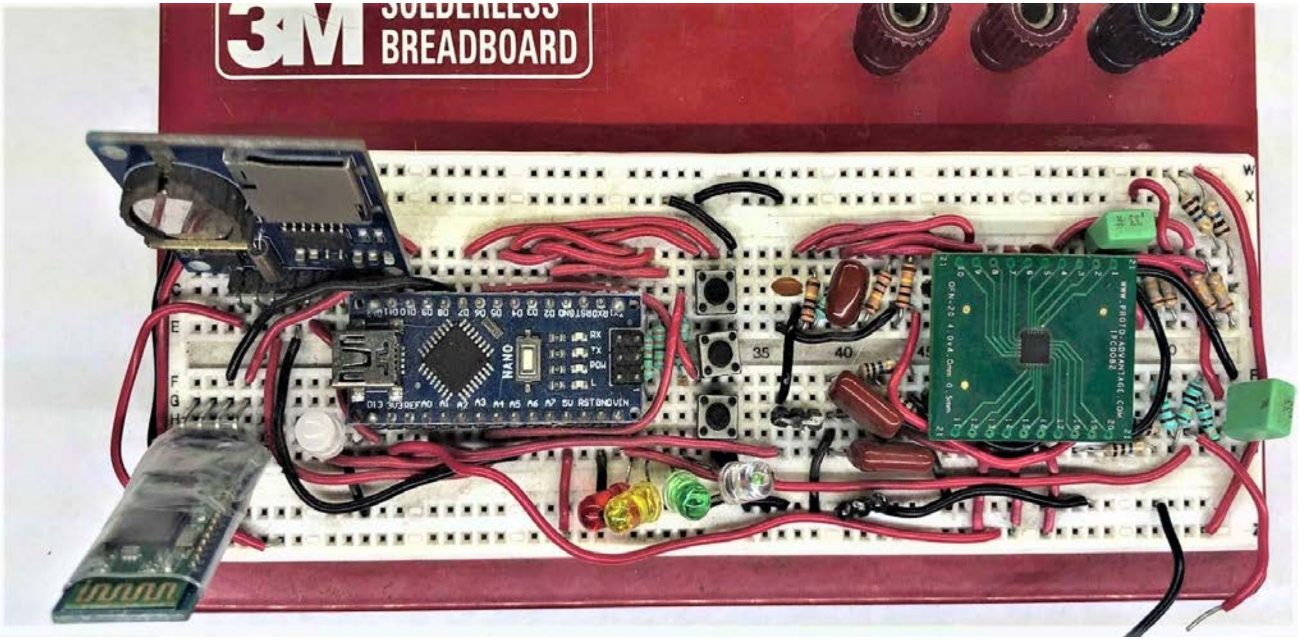


Figure 14. Long-time recording ECG Breadboard prototype with Bboards.

PCB AND PROCESS

Component placement

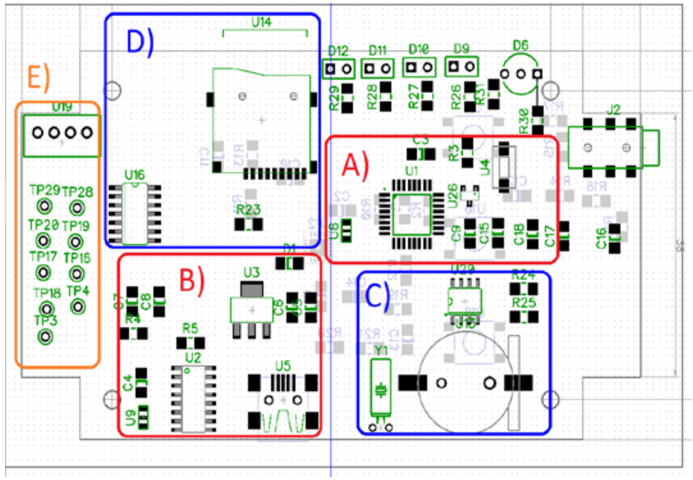


Figure 15. Component section: A) and B) Arduino Nano, C) and D) Data logger shield and E) HC-06 Bluetooth module and input, output, power and ground ports.

PCB design

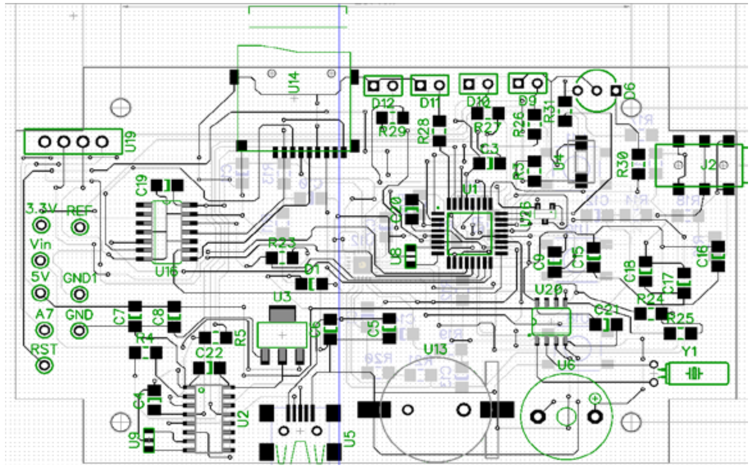


Figure 16. PCB circuit design in DIPTRACE software.

3D model PCB

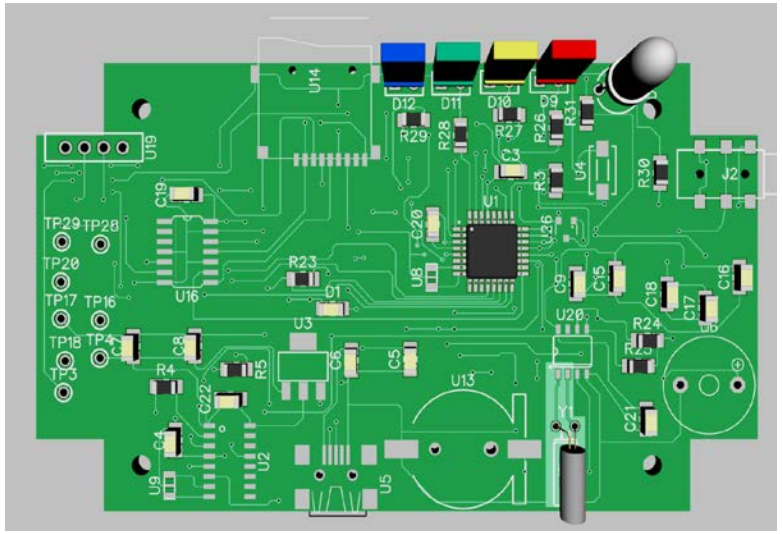


Figure 17. Custom PCB top view in 3D before manufacturing.

PCB AND PROCESS

Components assembly

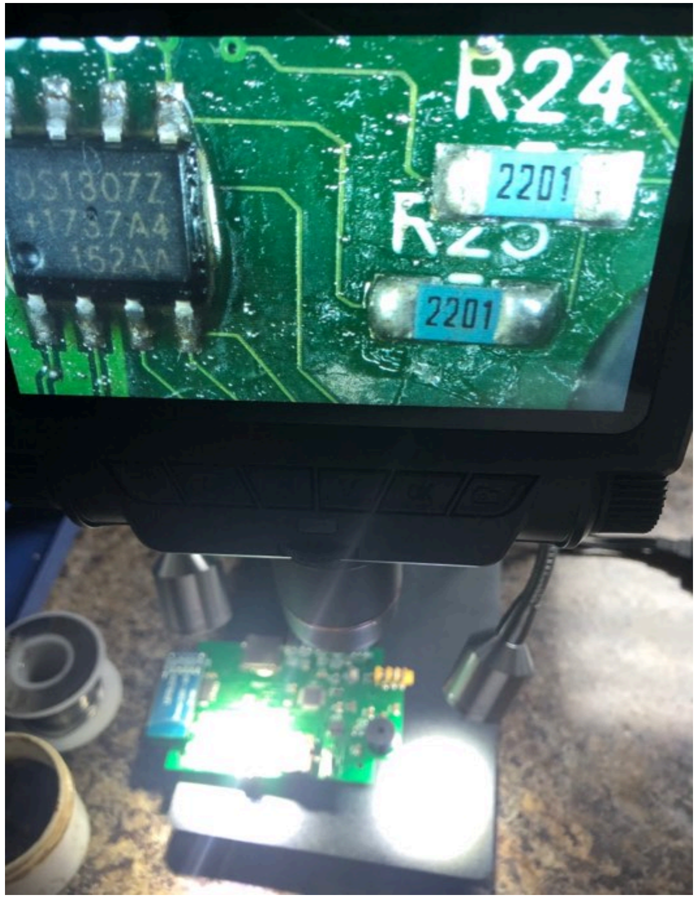


Figure 18. Amplification station for surface mounting Andostar ADSM301.

Final Custom PCB

A)

B)

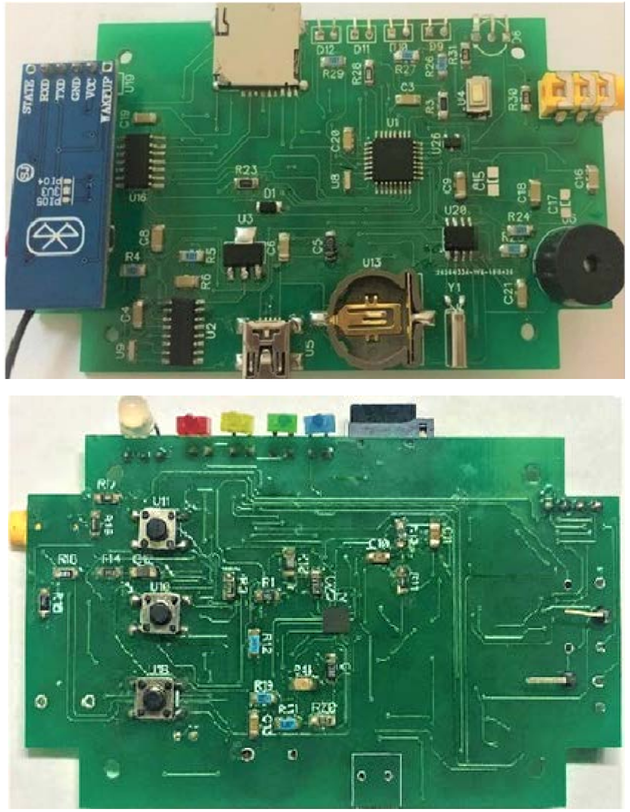


Figure 19. A) Printed circuit board (Custom PCB) top view, and B) bottom view.

BUFFER OVERRUN PROBLEM

- When reviewing an ECG signal recorded in SD memory, it was observed that a peak of the QRS complex was not recorded complete.
- Random phenomenon, without a pattern, sometimes 1 or 2 times / hour.
- Events of 36 lost samples on average in a 1 or 2 hours ECG records.

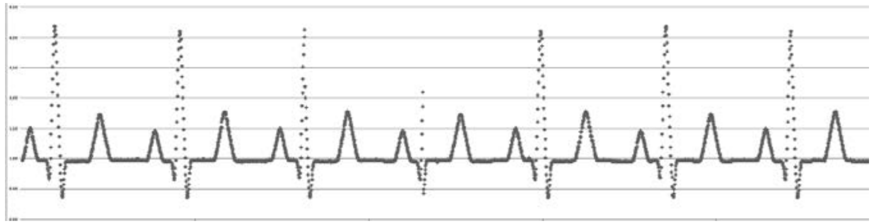


Figure 19. Atypical event in the QRS interval in the ECG signal.

Table 3. Characterization of the atypical event of the QRS complex in long-term ECG records.

Archive	Data points	Samples lost	% of lost samples
1 hour at 360Hz	1,288,907	41	0.00318%
1 hour at 500Hz	1,784,059	49	0.00274%
2 hours at 360Hz	2,579,257	31	0.00120%
2 hours at 500Hz	3,568,588	34, 27	0.001709%

Through an experiment design, it was ruled out that the error is due to:

- ✓ Function generators.
- ✓ Error by Arduino Nano module, using other modules of the Arduino family.
- ✓ Hardware error in datalogger module.
- X Memory microSD card error.

Arduino libraries work with 1 write buffer. A program was implemented to measure the latency time in microSD writing (Table 4), it was observed that when having a longer writing latency time the number of atypical data increased. If the latency of writing is high it can cause loss of information.

Table 4. MicroSD memory write latency.

Capacity	Brand	Class	Write latency
1gb	Sandisk	4	5312μs
2gb	Nokia	2	6312μs
2gb	NA	2	6840μs
4gb	Sandisk	4	8240μs
4gb	Kingston	10	4584μs
16gb	Sandisk ultra	10	5312μs
32 gb	Sandisk	4	6464μs

Atypical event

- Visual inspection of a record takes a long time and is tedious, automatic analysis alternatives were evaluated to detect these atypical events by introducing a control ECG signal with known atypical events.

- Five software / Algorithms were evaluated to determine which could help detect atypical events accurately. The options were: BioSigKit, Pan Tompkins Algorithm, nQRS detector, simple QRS for MATLAB, and Biomedical Workbench of LabVIEW.

- The two options that had no errors when counting atypical events were: **1) Pan Tompkins Algorithm and 2)Biomedical Workbench.** Which then were used to verify error-free recordings of the MicroSD memory card.

5 atypical events

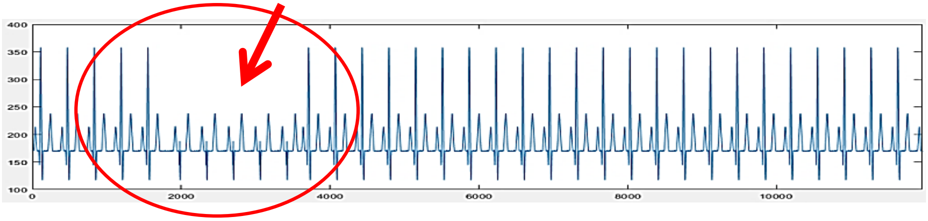


Figure 20. Control signal with five atypical events.

Table 5. Software and algorithm evaluation for automatic ECG signal analysis.

Archive	QRS peaks control signal	MATLAB								LABVIEW	
		BioSigKit		Pan Tompkins		nQRS detector		simple QRS		Biomedical Workbench	
		Detected	Error	Detected	Error	Detected	Error	Detected	Error	Detected	Error
1 hour without events	3600	3600	0	3600	0	3600	0	3601	1	3600	0
1 hour with 5 events	3595	3596	1	3595	0	3599	4	3598	3	3595	0
2 hours without events	7200	7200	0	7200	0	7200	0	7201	1	7200	0
2 hours with 5 events	7195	7196	1	7195	0	7199	4	7198	3	7195	0

Solution implemented:

- Double buffer implementation using available RAM memory to avoid data loss.

Instructions	BUFFER_BLOCK_COUNT0 (512 bytes)	BUFFER_BLOCK_COUNT1 (512 bytes)
1	Capture ADC data (Interrupt mode sampling rate filling buffer)	Waiting (Empty buffer)
2	(Writing data in SD) (Releasing buffer)	Capture ADC data (Interrupt mode sampling rate filling buffer)
3	Waiting) (Empty buffer)	(Writing data in SD) (Releasing buffer)
4	Capture ADC data (Interrupt mode sampling rate filling buffer)	(Waiting) (Empty buffer)

Figure 21. Two buffers operation for writing data in SD memory.

Performance tests:

- Long-term ECG records were recorded using double write buffer (1,2,12, and 24 hours at 500Hz).
- Low and high latency write memories were used.
- Records were reviewed with automatic analysis methods.
- The occurrence of atypical events in all records was eliminated.

ECG Signals:

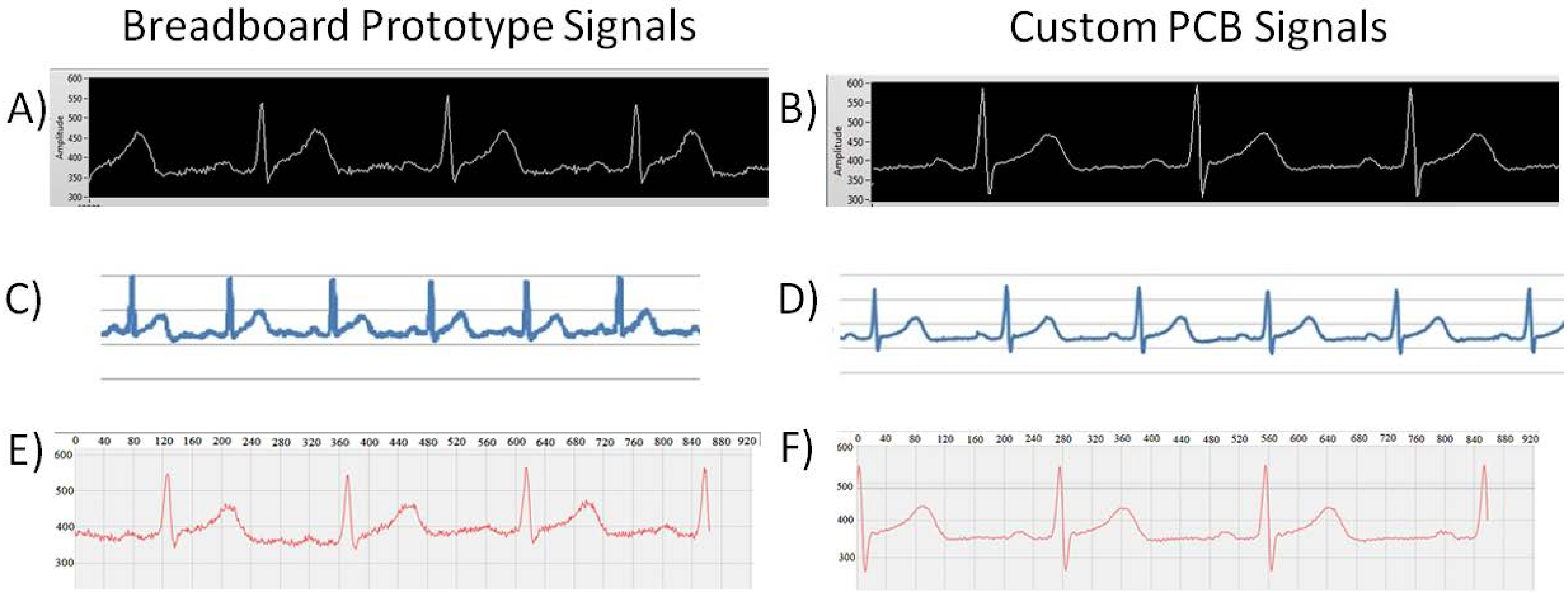


Figure 22. Snapshots of different operation modes. A) ECG signal transmitted by serial cable (breadboard prototype), B) ECG signal transmitted by serial cable (custom PCB), C) ECG recorded to a microSD card (breadboard prototype), D) ECG recorded to a microSD card (custom PCB), E) ECG signal transmitted by Bluetooth via smartphone (breadboard prototype), F) ECG signal transmitted by Bluetooth via smartphone (custom PCB). The sampling frequency in all signals was 360 Hz.

Basic safety and performance

Table 6. Approval of ANSI / AAMI / IEC 60601-2-47: 2012 regulatory requirements

Parameter	ECG base en breadboard
Application	Monitoreo
Bandwidth	0.5Hz-40Hz
Gain	1100
Sample Rate	360-2100Hz
Dynamic Range of Operation	0-3 mV
Patient Leakage Current	1-2 µA
CMRR	88.7dB
Input Impedance	10MΩ
Signal Noise	20µV
Offset DC	±300mV
Recording Time	29 Hrs.
Component Accuracy	1% Resistors 5% Capacitors

Table 7. Standards of quality and safety standards for the development of an electrocardiograph.

Name of Standar	Regulation
IEC 6060-1 parte 1 [23].	Electromedical equipment parts 1: General requirements for basic safety and essential operation.
ANSI/AAMI/IEC 60601-2-47:2012 [24].	Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
ANSI/AAMI C12:2000/ (R) 2010 [25].	Disposable electrodes

CONCLUSIONS

The results indicate that the AD8232 microchip is suitable for the AFE function, as it delivered a useful signal for a long-term single-lead ECG monitoring application. The ATmega328 microcontroller on the Arduino open-source platform also provided satisfactory results. With its various communication protocols, the microcontroller kept the fabrication cost low, maintained portability, and reduced the number of components and the design time of the prototype. The total cost of the prototype components was 20 USD; this renders a personal monitoring ECG system with prolonged recording time accessible to a larger sector of the population. This design does not seek to replace hospital equipment but can support the diagnosis, prevention, and management of cardiovascular disease

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