A Low Cost IoT Enabled Device for the Monitoring, Recording and Communication of Physiological Signals

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Abstract: The physiological information obtained from patients during rehabilitation tasks with robot-assited platforms is essential to carry out them properly. It has been shown that an environment adapted to the needs of each patient favors their involvement and leads to a reduction in rehabilitation times. In order to be able to control the degree of involvement of the subjects at all times and subsequently adapt certain parameters of the rehabilitation task, physiological signals such as ECG, GSR (Galvanic Skin Response) or SKT (Skin Temperature) are used. A low-cost device that integrates sensors for reading and recording the ECG and GSR signals, which subsequently communicates via WiFi to a cloud-based environment is proposed in order to carry out online data processing and dynamically adapt upper-limb rehabilitation tasks.

1 INTRODUCTION

In recent years, different biomedical devices have been used to analyze certain physiological signals used to control rehabilitation environments with robotic platforms.

Activity trackers and other wearable electronic devices have gained popularity due to users' desire to monitor, measure, and track using various real-time features related to their fitness or health, including the number of steps,heart rate, heart rate variability, body temperature, activity and/or stress levels, etc. (Conchel, 2018).

The importance of analyzing this type of physiological signals in our study lies in the direct relationship that exists between the stress level of a subject and the HRV (Hate Rate Variability) (Domen, 2011) and GSR (Galvanic Skin Response) (Guerrero, 2013) measurements. Stress is a physical, a mental, or an emotional factor that causes bodily or mental tension. Stresses can be external (environmental, psychological, or from social situations) or internal (illness or caused by a medical procedure). There are different methods to detect and determine the stress level, being the most used: measuring the cortisol level, the heart rate variability, or the electrodermal activity (Wu, 2018). In other way, the study of Kutt supports the use of Heart Rate (HR) and Skin Conductance/Galvanic Skin Response (GSR) signals to validate semantic emotional descriptors based on valence and arousal measurements, linked to the user's involuntary reactions transmitted by the Autonomic Nervous System (ANS) (Kutt, 2018).

In our case, the heart rate (determined by the electrocardiogram, ECG) and the electrodermal activity (obtained from the galvanic skin response, SR) have been chosen to determine the stress level of a subject and their emotions during upper limb rehabilitation tasks. An example of an application to record the ECG and GSR in a wearable device can be found in (Rosa, 2019) and (Crifaci, 2013) applied to anorexia nervosa adolescents. The results of this study determined that wearable sensors used were feasible, unobtrusive and therefore extremely suitable for young patients.

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After a systematic review of the most popular physiological signal recording devices, we determined the following ones are the best choices right now on the market:

- Consensys Bundle Development kit (Shimmer): an 'all in one' solution which enables the user to experience the full sensing capabilities of the Shimmer3 platform which includes the complete set of our Shimmer sensors (IMU, ECG, EMG, GSR), hardware and software (Oreto, 2006).
- AutoSense: an unobtrusively wearable wireless sensor system for continuous assessment of personal exposures to addictive substances and psychosocial stress as experienced by human participants in their natural environments (Ertin, 2011).
- Ring: a mobile and robust bio-signal measurement device for monitoring the skin conductance (using an electrodermal sensor, EDA and agalvanic skin response meter, GSR) and the cardiovascular activity (using a blood volume pulse sensor, BVP) (Mahmud, 2019).
- E4 wristband: a wristband medical-grade wearable device for real-time physiological data acquisition and visualization, enabling researchers to conduct in-depth data analysis (Mccarthy, 2016).
- Zephyr Performance Systems: measure six key inputs that report on more than 20 biometrics. Is a wearable technology built on clothes made for sport challenges (Nazari, 2018).
- Checkme Lite: a monitor for measuring, monitoring, reviewing and storing three physiological parameters in the home: ECG, pulse oxygen saturation (SpO2) and blood pressure variation (Drzazga, 2018).
- BITalino: a hardware and software toolkit that has been specifically designed to deal with the requirements of body signals (Da Silva, 2014).

A more exhaustive comparison can be seen in Sumit Majumder's review (Majumder, 2017).

Usually, the devices for recording these signals are expensive and are not wearable, which makes it difficult in many cases to carry out rehabilitation tasks in a simple and comfortable way for both the subject and the therapist. So, what makes a device fit for the purpose of affective health research? (Coghlan, 2009):

- Accuracy. The devices should be low-cost to be accessible to almost anyone without compromising the fidelity of the results.
- The device is expected to collect data continuously without interfering with the user's day-to-day tasks. The platform must be mobile, comfortable, robust in regards to prolonged sensor contact, and have a sufficient battery-life to last throughout the day.
- Connectivity to other devices e.g. through Bluetooth or WiFi.
- Access to raw data so it can be processed post-recording without losing any data from the original signal.
- Easy to clean and disinfect between subjects.

This work focuses on the design and manufacture of a low-cost device made with 3D printing, making use of basic electronics based on an Arduino-like microcontroller, the AD8232 sensor module for measuring the physiological signal ECG and Grove GSR v1.1 for measuring the GSR. The microcontroller integrates a WiFi Soc solution providing a reliable performance in the IoT, which is used for communication with the Thinger.io platform. A Nextion 3.2" resistive touch screen is used for the configuration of initial parameters and online visualization of the signal records. We have called this device Trazein (registered trademark).

2 DEVICE SPECIFICATIONS

2.1 Design and Materials

When designing the device, the specifications shown in Table 1 have been taken into account, complying with the requirements cited in (Coghlan, 2009) and expanding with what we have considered certain innovative improvements that will be justified in the following sections.

Table 1: Device Specifications.

Manufacturing	Accuracy	Portable	Connection	Data Access	Price	Intuitive
3D Print	ECG: AD82323 GSR: Grove	110x80x35 mm 80 gr Fit to wrist	WiFi: ESP8266 Serial: Micro USB	Download in .txt/.csv format	<50$	HMI: Nextion 2,4" TFT touch Screen

It is clear that today one of the most widely used rapid prototyping technologies is additive manufacturing. The flexibility obtained when making any model with 3D printing is much greater than making molds for plastic injection (Cano, 2019). For this reason, it is very important to take the design into account in the preliminary phase, paying special attention to both the benefits of this technology and its drawbacks.

The design of this biomedical device has been made with Fusion360, an Autodesk distribution that covers the entire process of planning, testing and executing a 3D design, being able to export the final model in a .stl file ready for laminate with a software of 3D printing, in our case Cura. Finally the impression was made on an Ultimaker 3s.

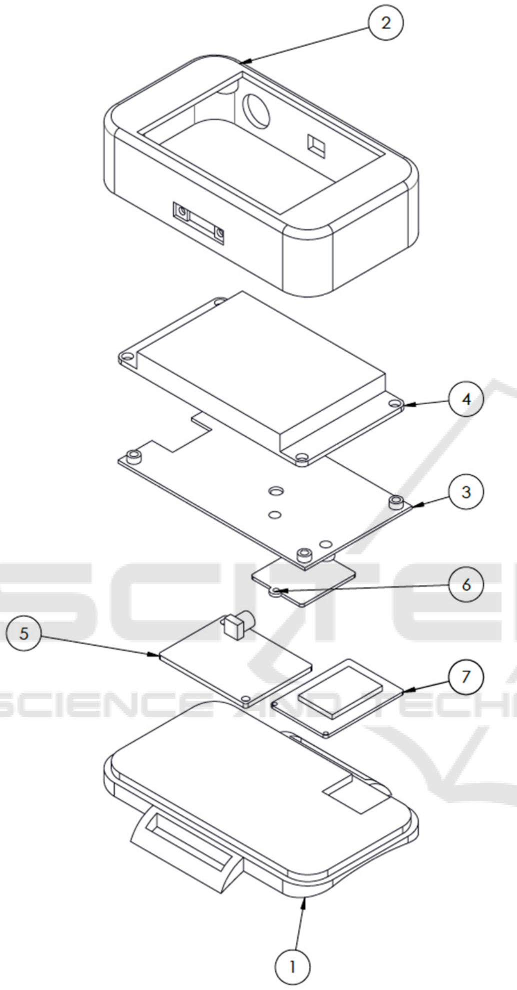


Figure 1: Exploded Device with Fusion360 CAD Software. “Fit to wrist” configuration.

The design is seen in Figure 1, where the different parts that make up the device are shown. The housing (2) is printed on Medical Smartfil material, a high-quality filament specially designed for medical applications. This filament has a USP Class VI or ISO 10993-1 certification, which guarantees that it is biocompatible with the human body (Ferrás, 2020), (Reeve, 2017). This type of technology with these materials has given good results previously, as shown in the study by (Aguado-Maestro, 2019).

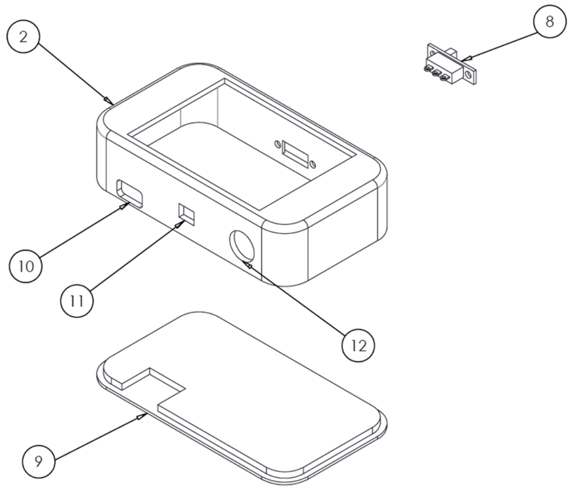


Figure 2: “Desktop” configuration as an alternative to “Fit to wrist” configuration.

The device housing is completed by a lower cover (1), also made of Medical SmartFil and with a completely ergonomic design adapted to the anatomy of most wrists. It has holes in its lateral projections to be able to adjust the device to the user, thus acquiring the quality of wearable. Inside it houses the electronics components: a microcontroller (7), an ECG signal reader (5), a GSR signal reader (6) and an HMI (Human Machine Interface) consisting of a touch screen (4). The electronics are separated by a plate made in 3D printing (3) and all components are properly screwed to the housing (2) or to the separation plate (3).

2.2 Comparision to Other Devices

The devices that currently exist for reading physiological signals, such as those that concern us in this case, can be divided into two large blocks: those that have the category of medical devices and those that do not.

Starting with the latter, they are generally known as wearables that can then be divided according to their use into sports-oriented or everyday wearable. These devices are characterized by a small and ergonomic size, at the same time they have an internal battery that usually lasts for several days between each charge and finally the cost is not usually high. On the contrary, these devices do not usually record any physiological signals except, in some cases the ECG, without offering the possibility of exporting the data to be able to store or process them externally to draw conclusions. Some examples are those shown in Table 2.

Continuing with those devices that fits the category of medical devices, they offer a greater range of signals to be read and recorded, with much more precision and more processing capacity. On the contrary, learning its use and operation is more laborious, having to resort, at times, to the presence of a specialist. They are not portable for the most part and require an external power supply, in addition to lacking Bluetooth or WiFi connectivity, so data export has to be done through a cable to a computer. The price is quite high as seen in Table 3.

Table 2: Most successful wearable devices on the market.

Weareable	Fitbit Charge HR	Jawbone UP24	LG G Watch R	Xioami Mi Band 5	Samsung Gear VR	Garmin Vivofit	Apple Watch 5
Price (euros)	120	60	280	35	250	115	490
Connectivity	BT	BT	BT	BT	BT/WiFi	-	BT/WiFi
Sensor	-	-	ECG	ECG	ECG	-	ECG

At Trazein, an ergonomic and portable design has been prioritized, with a reduced weight of 80 grams and dimensions of 110x80x35 mm. There are two types of configurations, either with a strap to place as a smartwach on the wrist, such as a blood pressure monitor, or with a rigid cover to place on a table or a horizontal surface. It has a switch on one of the sides to interleave between the two phsyiological signals (ECG and GSR) to be recorded, which are connected to the same analog input port of the microcontroller. On the other side, there are three connectors, two for each of the sensors and another for a micro-USB cable that is used to connect an external power supply.

Table 3: Most successful medical devices on the market.

Biomedical device	Consensys	Bitbrain	Empatica	AutoSense	E4 Wristband	BITalino
Price	2.800	1.300	-	-	1.690	199
Sensor	ECG/GSR/PPG	GSR/PPG	GSR/PPG	ECG/RIP/GSR	ECG/PPG/EDA	EMG/ECG/EDA
Physical device	YES	YES	YES	NO	YES	NO

It has a touch screen that acts as an HMI, which is located below the level of the casing in its upper part, to avoid breakage or scratches in case of falls or bumps during transport. We consider that having a touch screen such as HMI is an added value for the subject when it comes to being able to view their physiological signals in real time, configure their record history or connect to the WiFi network without having to have a computer.

2.3 Manufacturing Specifications

Within the field of additive manufacturing, or manufacturing using 3D printing, there are different types of technologies (SLA, SLA and FDM). It is important to choose the appropriate technology based on the compromise that must exist between the cost of the device, the final properties of the product part and the manufacturing time. The choice of this manufacturing mode has been selected for several reasons (Ngo, 2018): low cost of the prototype, flexible and personalized manufacturing when obtaining a model designed using a CAD program, ease of manufacture and material savings.

Table 4: Parameters for 3D printing manufacturing.

Quality	Perimeter	Filling	Velocity	Support	Material
Layer height: 0,1 mm.	Wall thickness: 1 mm.	ρ of fill: 40 %.	Printing speed: 80 mm/s.	Bracket extruder: Nº 1.	Printing temperature: 250 °C.
Initial layer height: 0,2 mm.	Upper / lower pattern: Lines, 3 layers	Fill pattern: triangles	Filling speed: 80 mm/s	Placement of the support / pattern: in all sites / lines	Print bed temperature: 60 °C.
Line/Wall width: 0,35 mm.	Nº of Wall lines: 3.		Velocity of displacement: 150 mm/s	ρ of support: 15 %.	Flow: 100 %.

For all this, our device has been manufactured using FDM technology using PLA as a construction material. As it is a device for use with people, this material is the one that best adapts, offering excellent properties at a low price compared to other traditional biodegradable polymers used in medical applications. Besides being environmentally friendly it is not toxic for use in contact with the human body (Lasprilla, 2012). Manufacturing conditions are also taken into account when selecting the material. By raising the temperature to get the material to be in a fluid state and to be extruded through the nozzle built into the print head, it causes certain volatile particles to be emitted into the environment. Specifically, with the material used in this project, studies have been carried out on the harmfulness of these gases emitted on human health. Determining that finally that these volatile compounds emitted into the environment during the printing of a 3D model do not pose any health problem (Azimi, 2016), (Riya, 2019).

In this way, we obtain a low-cost [50 eur] device with a reduced manufacturing time [6 hours] and technical specifications that make it very convenient to be able to house the necessary electronics and be used in any rehabilitation environment. Thanks to its size and weight, it is a portable device, and due to its simplicity, it can be used without the need for prior knowledge. The design made specifically for 3D printing makes it easy to manufacture in any type of printer, optimizing the amount of material used by not requiring hardly any support material.

The parameters used in the Ultimaker Cura v.4.7.1 lamination software that we consider to be optimal to obtain a high-performance device and also taking into account the conditions recommended by the manufacturer are those shown in Table 4.

2.4 Electronic Specifications

When selecting the electronics that the device should include to meet the specifications, we chose the following: AD8232 module for reading the ECG signal, Grove GSR v1.1 module for reading the GSR signal, a WEMOS D1 MINI development board based on ESP8266EX microcontroller and finally an HMI composed of a Nextion NX3224T024. The scheme is shown in Figure 3.

- **ECG Module.** AD8232 Heart Rate Monitor (Sparkfun^{TM}) module is used for measuring the ECG and determinate the heart rate of the user. The ECG module is based on the AD8232 (Analog Devices), an integrated circuit with specially calibrated signal amplifiers and noise filters for ECG signals. The module suppresses the 60Hz noise generated by household electricity. The module provides an analog output so an analog-to-digital conversion must be performed to process and display the ECG on the HMI. Examples of investigations that have used this module are (Gifari, 2015), (Lu, 2014), (Mishra, 2018) obtaining promising results:

Table 5: ECG bandwith specification.

Application	Bandwidth (Hz)
Display	0.5-40
QRS Detection	0.5-40
Arrythmia detection	0.05-60
ST segment monitoring	0.05-60

According to (Rachit, 2020), ECG bandwidth specification is dependent with its application and it is presented in table 5. Table 6 shows a comparison of different chips for ECG measurement. AD8232 have been chosen over other chips for the following reasons: HM301D is three channels, while we only need a single channel ECG for QRS detection; ADS1191 doesn't provide high enough gain to get good resolution; AD8232 has the best output impedance and gain.

Table 6: Comparison between most used ECG microchips.

Parameter	*Chip*		
	AD8232	*HM301D*	*ADS1191*
Company	Analog Devices	ST Microelectronics	Texas Instrument
SMRR	80 dB	100 dB	95 dB
Output Impedance	10 GΩ	50 MΩ	100 MΩ
Gain	100 V/V	64 V/V	12 V/V
Feature	Rail to rail output	3-channel ECG	Low noise PGA
Price	$ 19.95	$ 125	$ 7.96

- **GSR Module.** The Grove – GSR sensor v1.1 module (Seeed) is used for measuring the electrical conductance of the skin to determinate the GSR. Grove – GSR sensor allows to spot emotions by simple attaching two electrodes to two fingers on one hand. These emotions can cause stimulus to the sympathetic nervous system, resulting more sweat being secreted by the sweat glands. Grove – GSR has been used in emotion related projects, as shown in (Anzanpour, 2015), (Zhang, 2019) and (Saputra, 2017).

- **WEMOS D1 MINI Development Board.** It is based on the ESP8266EX, which is a low-cost WiFi microchip, with a full TCP/IP stack and microcontroller capability, produced by Espressif Systems. It is commonly used for a wide variety of projects, among others those related to communication in home healthcare environments, as shown in (Rachit, 2020) and (Mesquita, 2018).

To tackle all the specification we design the hardware using a step-by step method. The design starts with level 0, continued by level 1, and so on until every level can be implemented using specific hardware.

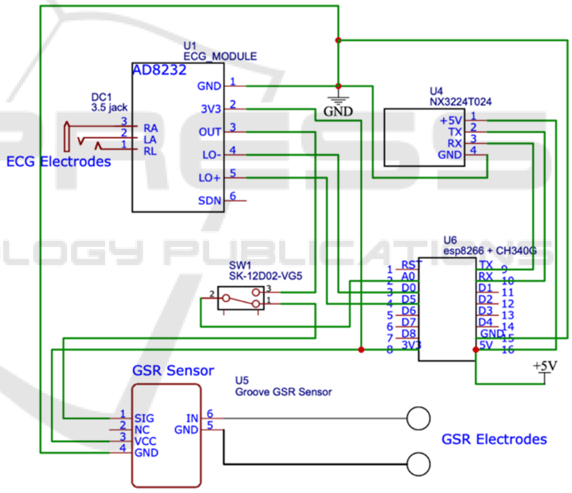


Figure 3: Electronic scheme for the Trazein device.

2.5 Connectivity and IoT

One way to introduce the project into the IoT environment is by incorporating a data collection and storage platform. This application is Thinger.io, presenting itself as open source and free of charge. The establishment of the connection between the device and the platform is through WiFi. Thinger.io is an open source software, and it offers an Arduino client library for connecting almost any Arduino board and other supported boards like ESP8266 for a simpler integration. It is possible to store time series data, identity and access management, even access by third-party applications, one of the advantages being the possibility of two-way communication between the elements in real time, with the REST-API method. The communication between the platform and the device does not imply a high consumption of energy, moreover, it is used efficiently.

All this is presented in a web interface where the user can manage all the resources, and even the possibility of making use of a mobile application where can be viewed the data collected in a simple and immediate way (Bustamante, 2019).

The maximum number of devices that can be connected to for free is 2, with 4 dashboards and 4 endpoints. Writing the collected data at least every 60 seconds in the storage bucket while the endpoint is every 10 seconds, storing a total of up to 10 value fields. All stored data can be exported in two very common formats for further analysis: text and comma separated values files (.txt and .csv).

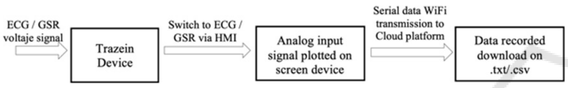


Figure 4: Functional Block of ECG/GSR Trazein device.

3 IMPLEMENTATION, TEST AND ANALYSIS

3.1 Manufacturing Results

The manufactured device looks like the one shown in Figure 5, with the ECG and GSR sensors connected as has been done in the patient trials.

The device has a highly ergonomic finish, which adapts easily to the wrist of the subjects regardless of their anatomy. The upper part has been coated with epoxy resin, to preserve the material after different uses. At the same time, the epoxy resin gives it greater resistance to impacts or accidental falls. The part that comes into contact with the skin has not received this treatment, to maintain the conditions described in the USP Class VI or ISO 10993-1 regulations.

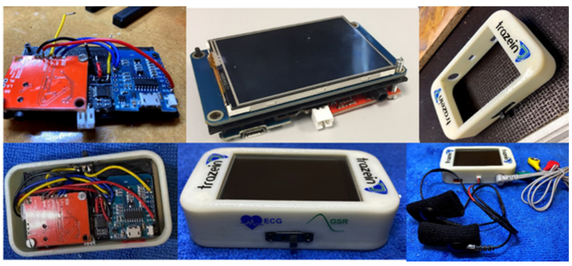
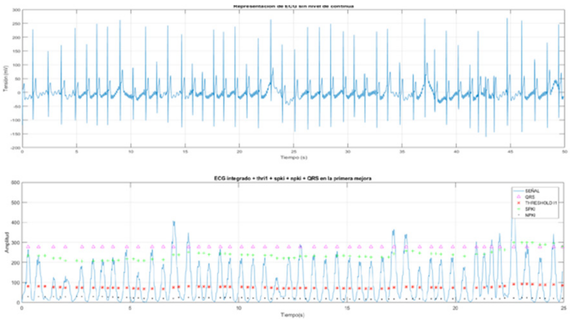
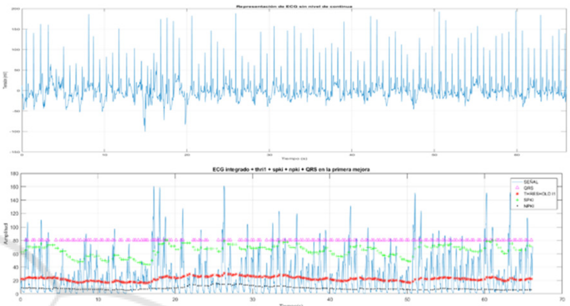


Figure 5: Final 3D printed manufactured device.

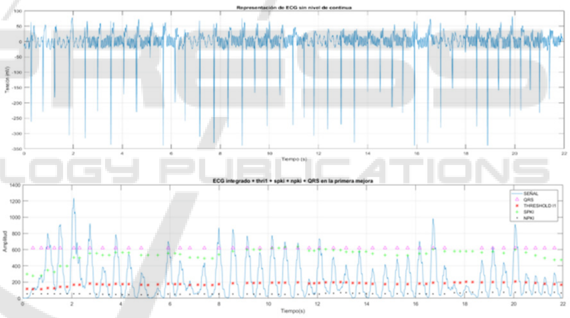
Subject 1: Age 22, Rest, 50 seconds.



Subject 2: Age 57, Rest, 65 seconds.



Subject 3: Age 59, Rest, 22 seconds.



Subject 4: Age 82, Rest, 22 seconds.

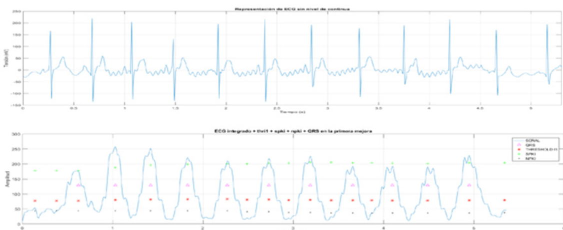


Figure 6: ECG signal sample acquisition and QRS detection for different subjects.

3.2 Experimental Protocol

When performing the proof of concept of the device, we have carried out an experimental study with 4 healthy subjects. The subjects ranged in age from 22 to 87 years, 2 males and 2 females. The tests were carried out under laboratory conditions, at an ambient temperature of 25ºC, in the FabLab facilities of the University of Valladolid. These tests consisted in measuring the heart rate and the galvanic response of the skin, in a resting situation in order to validate the correct functioning of the device in reading, sending and storing physiological signals, observing the different values obtained and comparing them with similar studies (Mochan, 2011), (Villarejo, 2012).

3.3 Test and Analisys

The results obtained from the recording of the ECG are those shown in Figure 6, while in Figure 7 the device can be seen in full operation with one of the subjects, showing the instantaneous recording of the ECG signal and the beats per minute (BPM) at rest.

The implementation of the Pam-Tompkins algorithm (Pan J., 1985), commonly used to detect QRS complexes in electrocardiographic signals, was carried out. In this way, we are able to obtain the BPM shown on the screen. It should be mentioned that the signal shown on the screen has not yet applied the algorithm and that its processing is carried out online on the ESP8266.

The results obtained from reading and recording the GSR are shown in Figure 8, where the horizontal axis is in units of time (seconds) and the vertical axis in units of resistance (ohms).

Figure 7: Trazein HMI showing ECG signal and BPM real-time acquisition with one subject.

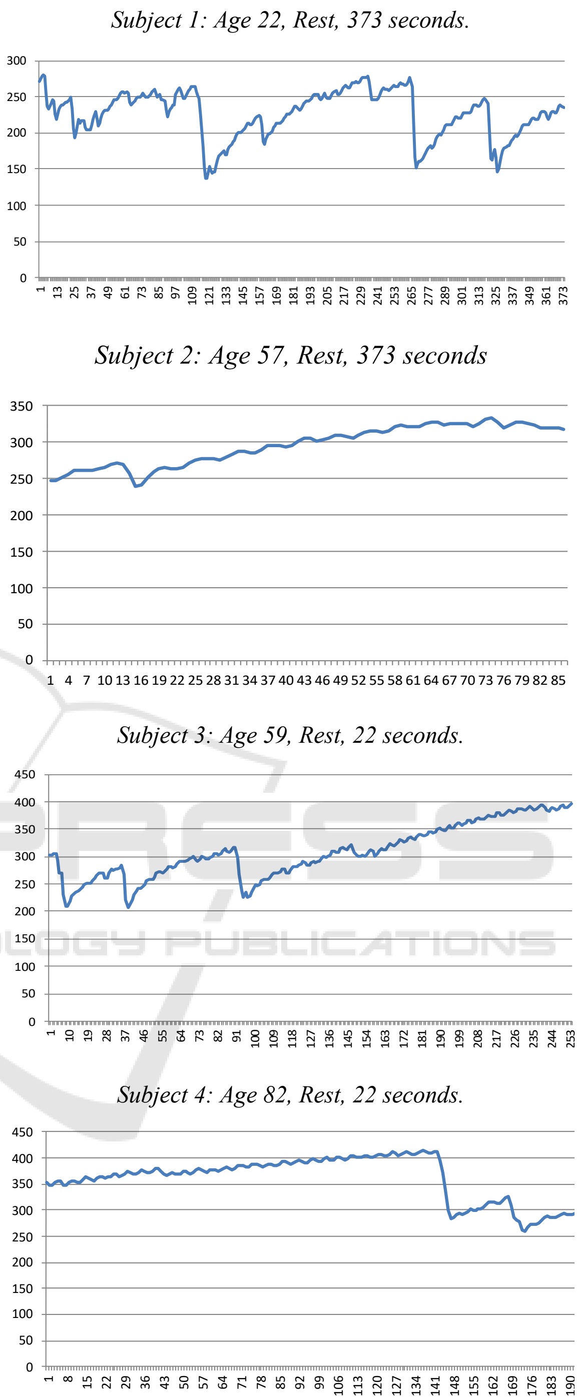


Figure 8: GSR signal sample acquisition for different subjects.

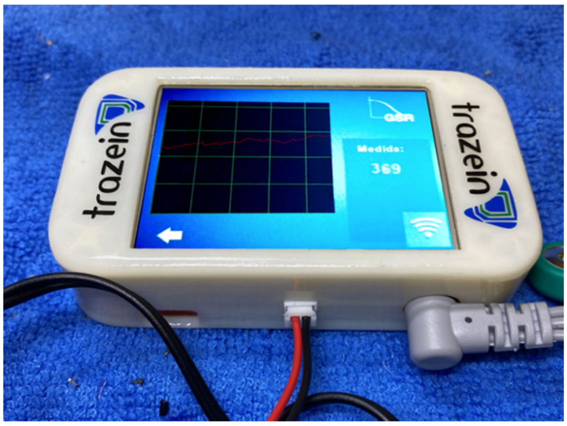


Figure 9: Trazein HMI showing GSR signal real-time acquisition with Subject 2.

4 CONCLUSIONS AND FUTURE WORKS

In this paper we have shown a new device for the acquisition, recording and sending of the ECG and GSR physiological signals. The novelty lies both in the design and manufacturing process, as well as in the concept of working in real time with cloud storage. The first refers to an ergonomic design, wearable type that adjusts to the wrist of any subject. Also, the configuration can be changed to be a desktop device. On the other hand, it is manufactured in 3D printing, in a time of 6 hours and with biomedical material that ensures safe contact between the device and the human body.

The second refers to a touch HMI that displays the physiological signals and displays the key value on the screen. While recording, it sends data packets to the cloud that are stored in the form of tokens, to be downloaded later in .csv or .txt format for later medical analysis. The implementation of the Pam-Tompkins algorithm in the ESP8266 microcontroller allows to process the acquired signal in real time and detect the QRS complex for the subsequent acquisition of the beats per minute.

The results obtained with the four subjects show the correct functioning of the device, being still necessary a validation against a commercial medical device to contrast results under the same conditions. Future lines of work go through experimentation with healthy subjects, being monitored at the same time by Trazein and Biopac MP150, in order to determine the precision of a low-cost device compared to a commercial one.

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