



PROTOTYPE OF A DEVICE FOR THE AUTOMATIC MEASUREMENT OF PHYSIOLOGICAL SIGNALS TO ASSIST THE DIAGNOSIS AND MONITORING OF PATIENTS WITH COVID-19

PROTOTIPO DE UN DISPOSITIVO PARA LA MEDICIÓN AUTOMÁTICA DE SEÑALES FISIOLÓGICAS PARA ASISTIR AL DIAGNÓSTICO Y SEGUIMIENTO DE PACIENTES CON COVID-19

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Abstract

This article describes the design, construction and preliminary results of a device to automate the measurement of physiological signals to assist in the diagnosis and monitoring of COVID-19. The device uses a system to controlling linear actuators to turn on/off certified biomedical instruments, in addition to algorithms for image recognition of displays with measurements of temperature, oxygen saturation, pressure and heart rate. The system also includes a mobile application, which receives data in real time and creates a database for medical evaluation. Results obtained with the device have demonstrated to provide a high percentage of efficiency in the data acquisition. After several trials with users, SUS and PSSUQ tests were applied to allow verifying the users' feedback regarding the satisfaction and usability of the prototype, with high score, showing the good acceptance of the device from the users.

Keywords: Automation, Covid-19, eHealth, image processing, SUS, telemedicine

Resumen

En el presente artículo se describe el diseño, construcción y resultados preliminares de un dispositivo para automatizar la medición de señales fisiológicas para asistir el diagnóstico y seguimiento de la COVID-19. El dispositivo utiliza un sistema para controlar actuadores lineales para encender/apagar instrumentos biomédicos certificados, además de algoritmos para el reconocimiento de imágenes de las pantallas de los instrumentos con mediciones de temperatura, saturación de oxígeno, presión arterial y frecuencia cardíaca. El sistema incluye también una aplicación móvil que recibe los datos de las mediciones a tiempo real y crea una base de datos para realizar una evaluación médica. Los resultados obtenidos demuestran un alto porcentaje de eficiencia en la adquisición de las mediciones. Después de hacer varias pruebas con usuarios, las evaluaciones SUS y PSSUQ permitieron verificar resultados satisfactorios respecto a la satisfacción y usabilidad del prototipo, demostrando la aceptación del dispositivo.

Palabras clave: automatización, COVID-19, e-Salud, procesamiento de imágenes, SUS, telemedicina

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1. Introduction

COVID-19 is a severe respiratory disease which originated in Wuhan (Hubei, China), starting an epidemic outbreak in December 2019. The World Health Organization (WHO) declared a worldwide health crisis in January 2020, due to the increasing global infection rates [1, 2]. In Ecuador, up to November 2021, the National Research Institute in Public Health (INSPI, Instituto Nacional de Investigación en Salud Pública) has recorded 526,615 cases with PCR tests and 33,219 confirmed deaths due to COVID-19 [3]. This disease attacks the respiratory system and among its most common symptoms it can be mentioned: fever, cough, headache, nasal congestion, fatigue, reduction of oxygen saturation, loss of taste and smell, syncope and deviation of gases in the blood [4–6]. Those who have acquired the disease show alterations in temperature, blood pressure (mainly hypertension), heart rate and oxygen saturation (due to the shortness of breath in severe COVID-19 cases).

In this scenario, the protocols recommended by health systems include measuring these physiological variables to make the diagnosis and prognosis of the disease [7, 8].

The technological advances are enabling to obtain data about the impact of the disease, and meet the requirements for taking care of the population during the pandemics [9]. For example, smartphones are tools that are being used to monitor physiological signals in various developments [10, 11], the use of wearable technology [12], the internet of things and big-data analytics [9], have a great potential for assisting in the diagnosis of diseases such as COVID-19, however, there are very few developments that integrate in a single system certified devices such as: digital oximeters, digital infrared thermometers and blood pressure monitors to acquire physiological signals of interest to create a medical history and databases relevant for decision making systems [13, 14].

Platforms for transmitting and storing data of a biomedical instrument (BI) [14] and developments that integrate networks for secure data communication [15, 16] demand robust digital telemedicine applications as fundamental resources for remote medical attention. Continuous monitoring with sensors and protocols for tracking through telemedicine platforms with internet of things, constitute valuable tools to reduce exposure and infection with COVID-19 of patients and medical staff [17–21].

With the objective of improving the protocols for diagnosis and treatment of COVID-19 with a technological tool, this work proposes the development of a portable device to carry out automatic measurement of heart rate, blood pressure, oxygen saturation level and body temperature. The device is based on the use of three certified BIs and an application to visualize

measured data and share them in a secure manner with health professionals for their evaluation. The development of this device and the tests conducted with the first prototype are described below.

2. Materials and Methods

Figure 1 shows the block diagram that describes the operation of the hardware and software stages of the device.

It includes a Raspberry Pi 3 B+ board (64 bits quad-core CPU, 1.4 GHz, 5 GHz wireless LAN, Bluetooth 4.2/BLE, Ethernet and PoE capability), three mini JS35A linear actuators of 12 V, 4 A (1.2 inches, 0.4 Nm, 0.6 inches/s, 0.07 kg).

The BIs are: a pulse oximeter (Jziki) which is adjusted to the index finger, an infrared thermometer (K&i), an automatic wrist blood pressure meter (URBEST) which shows systolic pressure/diastolic pressure/pulse rate.

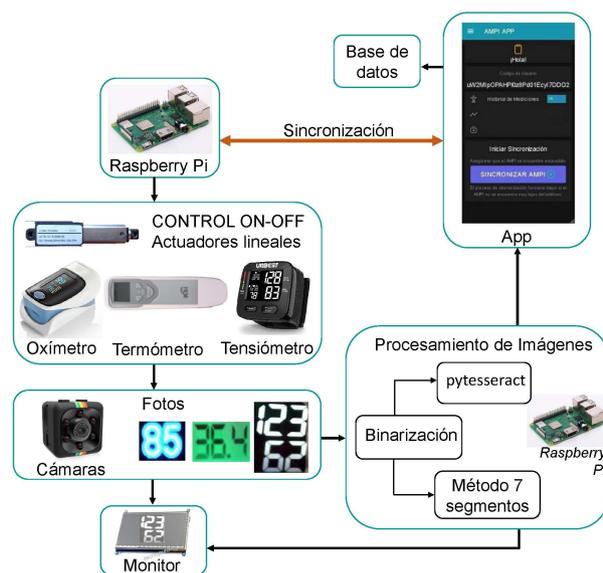


Figure 1. Block diagram of the device

It also includes three 12 megapixels 4032×3024 Opticam SQ11 minicameras and a 3.5" 320×480 P Raspberry touchscreen LCD monitor.

Measurements are made with the BIs placed on a metallic structure designed such that the actuators activate them to carry out the measurements automatically on the user's left arm. The BIs are not disassembled nor internally manipulated to guarantee the reliability of the measurements.

To start the measurements, it is necessary to synchronize the App with the Raspberry, and this enables to send the command to activate the BIs. After automatic start, measurements are made and the images from the screen of each BI are captured.

The images acquired are processed in the Raspberry PI for recognizing the value of the measurement carried out.

The monitor in the device enables visualizing the screen of the BIs during the measurements, for three periods of time. It starts with the thermometer, then the oximeter and finally it shows the screen of the blood pressure meter.

After measurements have been recorded, they are visualized in the monitor, and this information is sent to an application that also enables to visualize the measurements and to send the records to a database.

The standards IEC 60601-1-2 (electromagnetic compatibility), IEC 60601-1-6 (usability), IEC60601-1-8 (alarms and indicators) and IEC 60601-1-11 (use of medical devices at home) [22] were considered for the design of the mechanical structure, the electronic system and the digital platform. All this with the purpose of obtaining a reliable and safe prototype.

2.1. Mechanical Structure

Figure 2 shows the complete design of the device mechanical structure in Autodesk Inventor 2020, which consists of 15 pieces assembled by pressure self-catching.

The structure is made of polylactic acid (PLA), printed in 3D using an Ender 3 pro. This material was chosen due to its ease for printing and high mechanical resistance.

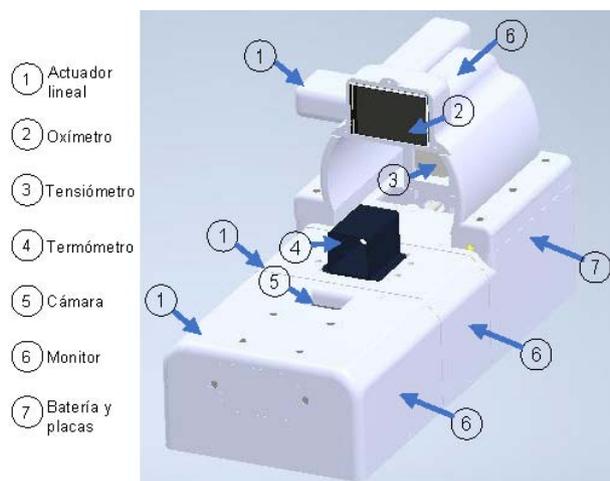


Figure 2. Design of the device and its components

The structure design was established based on the dimensions of the BIs and on the 50th percentile of anthropometric measures, with manual adjustment to the remaining percentiles. In this manner, the structure enables complying with the measurement protocols of each BI such that users place their left arm and the measurements are taken correctly.

The oximeter is located in the right side of the structure, to direct the index finger without requiring to apply pressure on the ends.

The thermometer is located in the proximal-palmar area of the hand for taking measurements.

The blood pressure meter is adjusted to the wrist according to the protocol of the BI.

The cameras are placed such that the image of the screen of each BI is acquired at a distance of 5 cm, without changes in the lightning.

The linear actuators have a stroke of 30 mm and have been placed horizontally on the structure in order to avoid overdimensioning it.

A sliding system was designed to transform a horizontal movement into a vertical one, to guarantee that the buttons of the medical instruments are operated safely.

Figure 3a shows the motor coupling, and Figure 3b shows the sliding system designed to generate a displacement of 4.5 mm to activate the medical devices.

Figure 3c shows the mechanism used to activate the on/off pushbutton of the blood pressure meter. The motor is coupled to element A which displaces horizontally to enable the sliding system (element B) to move in vertical direction, as shown in Figure 3d. This mechanism is replicated to activate the thermometer and the oximeter.

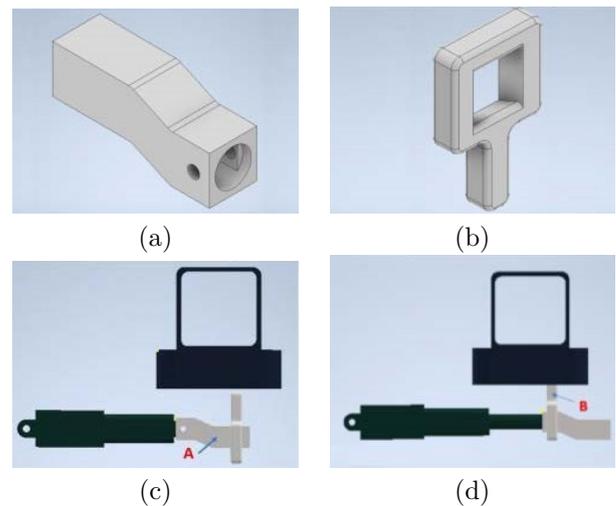


Figure 3. Mechanical elements to transform the horizontal movement of the motor into vertical movement of the sliding system (a) Motor coupling; (b) Sliding system; (c) Sliding system at the initial position; (d) Sliding system at the final position.

2.2. Electronic System

The electronic system consists of circuits to regulate the supply to the BIs and the boards (5V and 3.3V), establish the power stage for actuators (H-bridge), perform the control and guarantee battery charge (with

leads to indicate full charge and discharge). The device is powered by a 12V 4.4A Li-ion 3S2P Model 18650-3S2P rechargeable battery (0.3 Kg; 115 mm × 20 mm × 70 mm). It has fuses and diodes for protection of the supply stage, and also patient protection systems, such as isolation from the connectors to prevent electric discharges. The device considers the use of supply systems compatible with standards of electric safety to guarantee protection of users.

The Raspberry is used for control. It has been programmed in Python to: a) synchronize the hardware with the application (App) that enables sending the command to start the measurements from the smartphone.; b) control the three linear actuators for turning on the measurement instruments and c) use the monitor. The electronic boards and the battery are placed on the structure of the device (see Figure 2).

2.3. Image Recognition

For recognizing the information of the measurements taken by the medical equipment from the images of their displays, it was necessary to adopt a method based on the graphical representation of the numbers that show the measurement.

There are instruments that present the information using a digital typography, as shown in Figure 4, or with a seven-segment display configuration, as shown in Figure 5.

For this reason, a recognition method was developed for the oximeter (with digital typography) and for the thermometer and blood pressure meter (with displays).

It may be seen in Figure 4 that each of the digits has a light blue contour and a color similar to white in the inside (step 1). In this case it is necessary to binarize the image with a detection process in a color range that for the image acquired is white. The result is shown in step 2. After the image has been binarized and with the digits in black, the optical character recognition (OCR) tool known as pytesseract is employed. This is an open-source resource that enables identifying characters directly from images with extension jpeg, png, gif, bmp, tiff and others with Python that uses the Google Tesseract-OCR engine [23, 24].

After processing, a function is created that takes the image of the picture and returns the text detected in the image. The result of this process is observed in step 3.



Figure 4. Recognition of numbers with digital typography

For recognizing digits from the seven-segment display, as shown in Figure 5, the image is first converted

to grayscale (step 1), as indicated in step 2, and then the image is binarized to black and white (step 3).

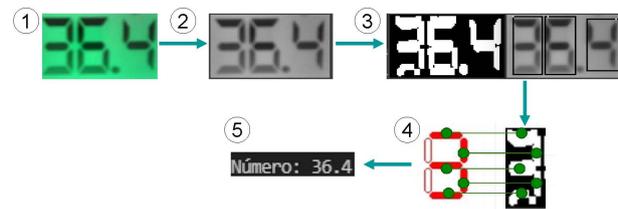
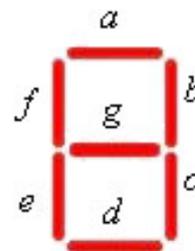


Figure 5. Recognition of numbers represented in a seven-segment display

Afterwards, it is used an algorithm designed to identify the region of each digit, as shown in step 4. For this purpose, the letters indicated in Figure 6a were assigned to each segment of the seven-segment matrix. Once the region of each digit has been identified, the critical points are compared with the table shown in Figure 6b, in which 0 represents a black pixel and 1 represents a white pixel. The comparison is carried out for each digit of the image and enables to obtain the result of step 5 (Figure 5) with the identification of the entire number.

Número	g	f	e	d	c	b	a
0	0	1	1	1	1	1	1
1	0	0	0	0	1	1	0
2	1	0	1	1	0	1	1
3	1	0	0	1	1	1	1
4	1	1	0	0	1	1	0
5	1	1	0	1	1	0	1
6	1	1	1	1	1	0	1
7	0	0	0	0	1	1	1
8	1	1	1	1	1	1	1
9	1	1	0	1	1	1	1



(a)

(b)

Figure 6. (a) Assignment of a name to the seven segments; (b) Table for comparing the segments identified for assigning the corresponding number

Once the numeric value of the measurement of each instrument has been obtained, the value is sent to the database of the App.

2.4. Digital Platform

Figure 7 shows the structure of the digital platform of the device, constituted by three subsystems.

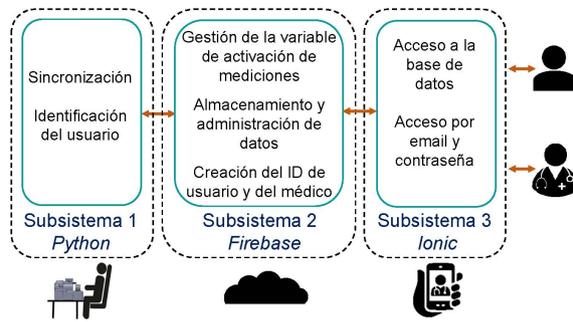


Figure 7. Subsystems of the digital platform

Subsystem 1, developed in Python, establishes the communication between the Raspberry Pi and the Firebase database (FDB) for synchronizing the device and verifying if there is a user in the database. When the Raspberry receives the signal to start the measurements, the device is activated (measurement instruments and image recognition) to send the measurement data and store them in the database. The data sent include the measurements of the three instruments, the measurement time and the user code. The code in the Raspberry Pi permanently listens and updates the changes of the variable that activates the process of taking measurements and sending them to the database.

Subsystem 2 was developed in the Firebase platform, which has a support for event listening and automatic update for Python. Two Firebase services were employed: a) Firebase Authentication, which enables saving and controlling recorded users' data, and linking this information to the database and b) Cloud Firestore which is a NoSQL database oriented to documents, that enables saving the measurement and the measurement initialization data.

Using these resources, the writing/reading of two FDB nodes (N1 and N2) is carried out with the Pyrebase library. N1 corresponds to "Device Status", which will give a signal to start the process for taking and recognizing the signals. N2, called "Unique user code", identifies the last user that synchronized the device with the App. The data writing has a function for storing the information in the FDB, which stores the data of the physiological signals measured.

Subsystem 3 consists of the App developed in Ionic (Open-source framework for developing mobile hybrid applications), to access the Firebase data in real-time and inform the user about the events for utilizing the device. The permanent listening of a Firebase Activation variable node is carried out at this stage, which permanently queries and updates the value of the "Device Status" variable of the FDB.

The App enables doing the registration, recovering user's password and starting the session to have access to the main menu. The menu gives access to the measurement history and to the synchronization of the App with the device. Each user should have a unique

code for activating the application, which is provided when the user creates an account. This unique code will identify the user and will be updated when he/she enters to the application.

A support menu has been programmed with information about device use, password change and personal data update. Data about the medical staff that will monitor the physiological signals is also required for managing user's data (identification and link with the device). In addition, each measurement record includes information about smell or taste loss consulted to the App, since these are relevant symptoms in the COVID-19 diagnosis [5].

2.5. Tests

Tests were carried out to verify the device functionality. These tests sought to determine: a) the time required by the device to record the physiological signals (body temperature, blood pressure and oxygen saturation); b) the error percentage of the tests to the image recognition system; c) evaluation of the App functionalities; d) evaluation of the device and the application by users according to the System Usability Scale (SUS) and the Post-Study System Usability Questionnaire (PSSUQ) and e) the error percentage in the measurements recorded in the app compared to the particular results of each instrument.

To estimate the time that the device will take to carry out a measurement, it is determined the time required by each process to complete correctly.

To verify the accuracy of image recognition, the values recorded in 20 photos obtained with the recognition algorithm were compared with the values recorded by a person while monitoring the measurement.

For App evaluation it was verified: correct registration and password recovery using a Google mail; database and storing service; information update in the database; service to share the measurement history; connectivity with the App in an operator data network, in a Wi-Fi network and with a weak connection signal; performance of the battery; if the device overheats and memory use.

Tests involved 16 healthy participants (7 men and 9 women, from 15 to 72 years of age), meeting biosecurity regulations and according to the following Test protocol: 1) The participants get an explanation about the operation of the device; 2) Each participant should sign a consent stating that he/she agrees with carrying out tests with the device; 3) Each participant is requested to access the App with his/her username and to synchronize the application with the device; 4) Each participant is requested to put his/her left arm in the device with the palm of the hand facing down and to close the band of the blood pressure meter as shown in Figures 8b and 8c; 5) Each participant is requested to make five measurements according to the

procedure for acquiring and visualizing the values of the physiological signals in the App; a rest of 180 s is taken between measurements; 6) Five measurements of the physiological variables are made using individually a blood pressure meter, a thermometer and an oximeter, according to the measurement protocol of each instrument; a rest of 180 s is taken between measurements; 7) After measurements are finalized, each participant is requested to answer the SUS and PSSUQ questionnaires to know the level of satisfaction with the algorithm corresponding to the method [25] and using the «PSSUQ Calculator» tool [26]; 8) The device is cleaned.

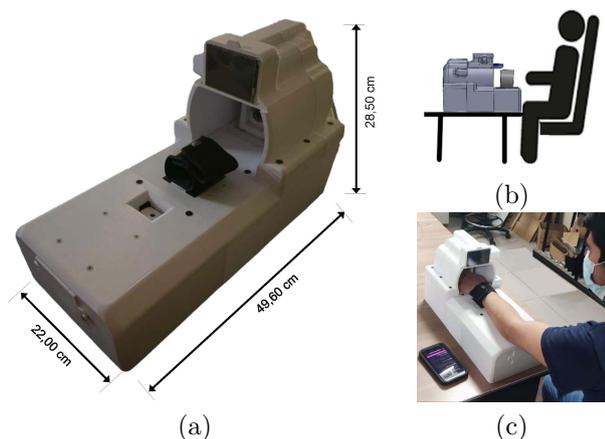


Figure 8. Prototype of the device (a) Integration of the elements and dimensions; (b) Correct position to take measurements; (c) User with his left arm in the device, with the blood pressure meter adjusted and the application synchronized for starting the measurements.

3. Results and discussion

Figure 8a shows the device with the integrated mechanical and electronic components. The dimensions of the device are 22cm × 49.60cm × 28.5cm with a weight of 1.125Kg. Considering that the BIs operate simultaneously, the total measurement time is estimated as the response time of the digital blood pressure meter, since this is the BI that takes the longer time to produce a response in its display. For this reason, it is considered that the device enables obtaining measurements of temperature, heart rate, blood pressure and level of oxygen saturation in 70 s. Since it is necessary to clean the device in case of various users, it is considered that the time required by a user to employ the device is 4 min. After cleaning the device with alcohol, it can be used again immediately. Based on this time, it is possible to make 12 consecutive measurements in an hour. Table 1 details the energy consumption of the device components, obtaining a total consumption of 3.20 Ah. Considering battery specifications and total consumption, the continuous operating time or autonomy is 1.37 h. For this reason, the device operates

without requiring power supply from the electric grid for a satisfactory time, thus fulfilling the portability and safety features according to standards such as IEC 60601.

Table 1. : Power consumption of the device during twelve measurements in an hour of use

Element	Time medición (h)	Current (A)	Consumption (Ah)
Raspberry	1,00	0,70	0,70
Actuator	0,02	0,04	0,48
Thermometer	0,005	0,36	0,36
Oxímetro	0,04	0,36	0,36
Blood pressure meter	0,075	0,6	0,60
Display	1,00	0,74	0,74
Total consumption			3,20

With respect to the recognition accuracy, when the response values of the recognition algorithm are compared with the values recorded during measurement monitoring, an accuracy of 100% was obtained. This success rate guarantees that the device records the values of commercial BIs integrated in a platform that stores the information for monitoring cases of COVID-19 and other respiratory diseases; it has been demonstrated that these data help in the diagnosis and that they are obtained securely. Regarding the operation of the App, it was verified that the access with authentication through e-mail and password is performed satisfactorily. Information about identification, service provider, date of account creation, last access data and unique user code are included during account creation.

Figure 9a shows the interface corresponding to the main page, which displays pages and main activities of the application, such as: greetings section, measurement history and synchronization with the device. Figure 9b shows the button for activating the device and starting taking physiological signals.

Figure 9c shows the information required to create the user's profile and Figure 9d shows an example of the measurements stored in the Firebase database obtained from the device.

During the tests, all measurements visualized in the display were sent to the database. This enabled verifying the correct operation of the digital platform for recording the measurements of all BIs. The App is simple and intuitive and constitutes an interface for the communication between user and device.

It was verified that the application works perfectly with different operating systems (Android and IOS) and from a web page.

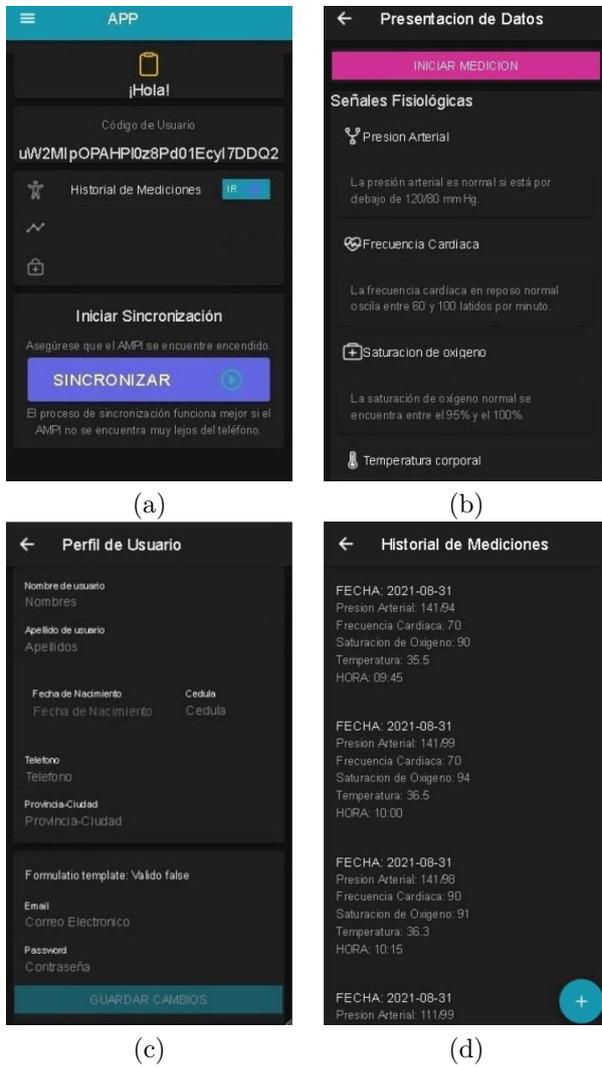


Figure 9. App Interface (a) Main page; (b) Interface to start the measurement; (c) User profile;(d) Measurement history

It was verified that the application works perfectly with different operating systems (Android and IOS) and from a web page. Similarly, the application works correctly with seven different smartphone brands. The average time to open the application and show the main interface is $3.25s \pm 1.75s$.

It was verified that no mobile device overheated and that the average battery consumption of the application is 5.10%. In case of using the total memory, it was verified an average use of 13 MB of RAM and 25.9 of storage. These results confirm that the application has a functionality of 100% and may be employed without problems in different mobile devices.

Regarding the device measurement accuracy compared with the measurements obtained using the instruments individually and manually activated, for oxygen saturation, heart rate and body temperature, the percentage of accuracy exceeds 98%. For blood pressure, the percentage of accuracy exceeds 96%. The

results also demonstrate that the device mechanical structure, which integrates the BIs and enables their automatic activation, does not alter measurement protocols. The BIs employed are described in different proposals as part of telemedicine and internet of things platforms. Although in the case of blood pressure it is recommended manual measurement [27], records obtained with digital systems are considered valid and useful in protocols for diagnosing and monitoring respiratory system diseases [19], [21], [28]. Therefore, the device developed is considered a contribution as a tool for assisting in such diagnosis and monitoring.

Table 2 shows the results of the SUS evaluation in which every participant answered ten questions using a scale from 1 to 5 (E1: totally disagree; E2: disagree; E3: neutral; E4: agree; E5: totally agree). The questions answered were: 1) “I believe that I would use this device frequently”; 2) “I find this device unnecessarily complex”; 3) “I believe that this device was easy to use”; 4) “I believe that I would need help from a person with technical knowledge to use this device”; 5) “The functionalities of this device are well integrated”; 6) “I believe that the device is inconsistent”; 7) “I Imagine that most of the people would learn to use this device quickly”; 8) “I find that this device is confusing”; 9) “I feel confident when using this device”; 10) “I needed to learn many things before being able to use this device”.

The SUS score calculated with the algorithm corresponding to method [25] was 82.50 ± 17.17 .

Over 60% of the participants think that they would use this device frequently, that it was easy to use and that its functionalities are well integrated.

Table 2. Results of the SUS questionnaire

Question	% E1	% E2	% E3	% E4	% E5
1	10	15	13	12	50
2	56	25	0	19	0
3	0	19	6	12	63
4	19	19	6	6	50
5	0	31	6	0	63
6	57	6	6	31	0
7	6	38	12	0	44
8	61	19	20	0	0
9	0	44	6	6	44
10	63	6	6	25	0

Regarding the PSSUQ questionnaire score, the result about App performance and satisfaction is 1.47. The usefulness of the system had a mean score of 1.25; the information quality obtained a score of 1.5 and the interface quality a score of 1.67. These results indicate that the application is at a high level of satisfaction and usability, since a smaller score between 1 and 7 indicates a better performance.

The participants initially thought that the device may be considered complex, however, the instructions provided, the availability of an operation manual and

the practice help users to easily use the device. However, half of the participants expressed that they would feel more secure with a professional guiding them. The group of higher age stated the need of having a person to assist them with the use of the App. This fact shows that new technologies must include a training aimed at the population who do not know about digital platforms. Considering the potential of applications in the middle of the pandemics and the new generation of health services [29], it is transcendental to boost the inclusion of digital alphabetization so that telemedicine proposals have a greater impact.

Another group expressed that manipulating a cell phone with only one hand may be difficult, however, the display facilitates starting the measurements and tracking the data obtained. This gives security to users, since some participants expressed that there were errors in data transmission, which demanded repeating the measurements. It is important to incorporate alarms and audio messages in the App as optional resources to guide those users that require additional help.

Overall, participants thought that the device is a good equipment; however, it is necessary to get used to have a device of this kind at home. A participant expressed being uncomfortable of not being able to see the hand during measurements, which states the possibility of considering new materials for the structure that enable visualizing the measurement process to guarantee confidence of users on the device.

It is necessary to conduct a study with population that already got infected with COVID-19, with the objective of analyzing the impact of the device as a tool to take care of this population.

It is considered that the proposed device constitutes a solid foundation to develop new platforms based on artificial intelligence and data analysis algorithms to diagnose asymptomatic cases of COVID-19, and to establish prediction models with data acquired in real-time [9], [20].

The availability of innovative resources in an accessible manner will enable strengthening health services in the future.

4. Conclusions

The proposed prototype of a device for automatic measurement of physiological signals of interest for diagnosing COVID-19 is easy to use, portable, non-invasive, guarantees measurement validity and patient safety.

The App enables the user to handle a medical history with key information for monitoring COVID-19 and other respiratory diseases. The usability tests were very important to know aspects to be improved in the mechanical structure and in the digital platform.

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