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TÍTULO: BABYMED: PULSE OXIMETER ADAPTED TO PREMATURE BABIES WITH LOW COST CRIB DEATH DETECTION

Trabajo de integración curricular presentado como requisito para la obtención del título de Ingeniera Biomédica

Autor:
Valenzuela Guerra Andrea Alejandra

Tutor:
Ph.D. Salum Graciela M., Bioeng.

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Dedicatoria

Dedico este proyecto de investigación a mis padres, por ser los principales motores de mi vida, porque han sido el ejemplo de superación y porque siempre han estado ahí para levantarme los ánimos y apoyarme en todo momento. A mis amigas y amigos que han estado durante todo este proceso. Además, a mis hermanitos de cuatro patas (Dulce, Chiqui, Peque y Free) que me acompañaron día y noche durante la realización de este trabajo.

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Resumen

El oxímetro de pulso es un dispositivo no invasivo que le permite determinar el porcentaje de saturación de oxígeno en la sangre mediante métodos fotoeléctricos. Esta es una herramienta indispensable en neonatología, principalmente en bebés prematuros. Un bebé prematuro es un bebé que nace antes de las 37 semanas completas de gestación y, en general, puede tener problemas para respirar y mantener una temperatura corporal estable. Por lo tanto, necesitan tener un mayor control y vigilancia de sus signos vitales por parte de un médico o de su madre. Los bebés prematuros tienden a tener problemas cardiovasculares y respiratorios durante sus primeros meses de desarrollo. Por eso se creó un oxímetro de pulso para bebés prematuros mismo que usa un método no invasivo, detecta la disminución de los niveles de saturación de oxígeno fuera de lo común y luego emitiría un tipo de señal o alarma a la madre, portátil para tenerlo en casa. Además, controla la saturación de oxígeno mediante una interfaz de computadora y permite guardar un historial médico del paciente. Asimismo, el dispositivo es de bajo costo para que tenga mayor alcance entre las comunidades de bajos ingresos.

Palabras Clave: oxímetro de pulso, saturación de oxígeno, frecuencia cardiaca, bebes prematuros.

Abstract

The pulse oximeter is a non-invasive device that allows you to determine the percentage of oxygen saturation in the blood using photoelectric methods. This is an indispensable tool in neonatology, mainly in premature babies. A premature baby is a baby born before 37 complete weeks of gestation and, in general, may have problems breathing and maintaining stable body temperature. Therefore, they need to have greater control and monitoring of their vital signs by a doctor or their mother. Premature babies tend to have cardiovascular and respiratory problems during their first few months of development. That's why a pulse oximeter was created for premature babies, which uses a non-invasive method, detects the decrease in oxygen saturation levels out of the ordinary, and then sends a type of signal or alarm to the mother, portable to keep at home. Besides, it monitors oxygen saturation through a computer interface and allows a patient's medical history to be saved. Also, the device is low-cost for greater outreach among low-income communities.

Key Words: pulse oximetry, oxygen saturation, heart rate, premature babies

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1. INTRODUCTION

A premature baby is the one born before completing 37 weeks of gestation. Premature birth is the worldwide main pediatric challenge and the leading cause of neonatal death. Similarly, it is the leading cause of long-term disabilities, such as mental retardation, cerebral palsy, hearing problems, vision, and chronic lung diseases (1). According to the age of gestation, the grade of prematurity can be divided into subcategories: extreme premature babies are babies with less than 28 weeks gestation, very premature babies are 28 to 32 weeks and moderate to late premature babies from 32 to 37 weeks (2) (Fig 1).

Figure 1. Premature Baby in a NICU. Author's own photograph.

The leading causes of premature birth, or reduction of the duration of pregnancy (preterm), are related to various factors such as environmental, socioeconomic, and educational. Some examples are the mother's malnutrition during pregnancy, infection both maternal, ovular, fetal or neonatal; multiple pregnancies; premature rupture of membranes; premature cesarean-induced prematurity; hypertension; physical effort and stress; alterations in the uterus, among others (3).

The consequences of being born premature baby are highly related to his respiratory and nervous system's immaturity. These problems can cause a low concentration of oxygen in the blood or hypoxemia (1). From this, many of the complications are derived as pathologies and syndromes, such as those presented in the following Table 1.

Table 1. Complications of a premature baby after birth (4).

Complication	Condition	Pathology
Respiratory	- Respiratory musculature weakness -Poor alveolar development - Surfactant synthesis deficit	-First cause of morbidity and mortality of the preterm -Pulmonary dysplasia
Neurological	-Immaturity of the Central Nervous System -Poor white substance myelination	-Susceptibility to hypoxemia
Cardiovascular	-Instability to increase oxygenation	-Early arterial hypertension
Gastrointestinal	-Slow evacuation -Poor bowel motility	-Necrotizing enterocolitis
Metabolic	-Low basal metabolism	-Poor insulin regulation capacity
Immunological	-Decrease of the inflammatory reaction	-Sepsis

1.1. Care in the Intensive Care unit

The NICU means Neonatal Intensive Care Unit. It is the place where babies born early or at risk are found (1). Being in the NICU, and especially if the baby is in critical condition, all the attention may be focused on the essential functions: that he breathes, that he has a heartbeat, and that he has the right temperature. For this, he will be connected to machines that specify these values. In order for a baby to leave the hospital, it must meet three objectives: maintain body temperature by itself, breathe properly (without apnea, with the capacity to breastfeed), and to have reached an appropriate weight around 1800 and 2200 grams (5).

After summarizing some generalities of premature babies and some of the technologies used, it is essential to highlight that the literature agrees that constant control of the premature baby should be maintained both within and outside the intensive care area. Breathing has been cataloged as a vital system since it is the most important thing to preserve a baby's life.

Premature children, due to their immaturity, have difficulties adapting to an environment outside the uterus. Consequently, its situation triggers several pathologies, mostly related to breathing. Respiratory pathology is the leading cause of morbidity and mortality of the preterm. It is associated with respiratory stress due to surfactant deficiency, followed by apnea and broncho-pulmonary dysplasia that appear in chronological sequence (6).

1.2. Biologic Principles

Pulse oximeters have the function of determining the amount of oxygen in the blood by measuring an amount known as oxygen saturation (SpO2). Oxygen saturation indicates the measure of the percentage of hemoglobin molecules bound to oxygen. This parameter is of vital importance when personal health needs to evaluate the respiratory function of a patient (7).

1.2.1. Oxygen

Humans depend on oxygen to live. All organs require oxygen for metabolism, but the brain and heart are particularly sensitive to lack of oxygen. In the body, when the oxygen saturation is short, it is called hypoxemia. A severe shortage of oxygen for a few minutes is deadly (8).

1.2.2. Hemoglobin

Hemoglobin is a vital protein that transports oxygen molecules throughout the body (Figure 2). Upon joining the blood changes color (7). Hemoglobin is proteins in the blood cells of vertebrate beings, which fix oxygen in the lungs and distribute it through the blood to the tissues. Besides, when returning to the lungs, hemoglobin has the function of carrying carbon dioxide from the tissues, and then the lungs eliminate it.

Hemoglobin is structured by two pairs of polypeptide chains and four heme prosthetic groups. The reduced hemoglobin is hemoglobin that does not have oxygen molecules. When each heme group is associated with an oxygen molecule, hemoglobin corresponds to oxyhemoglobin. The oxygen taken by inspiration passes from the alveoli to the blood inside the capillaries, while the carbon dioxide performs the reverse process, from the capillaries to the alveoli. The cardiovascular system has the function of managing the nutrients and oxygen these tissues need for the proper maintenance of normal cellular function (7)(9).

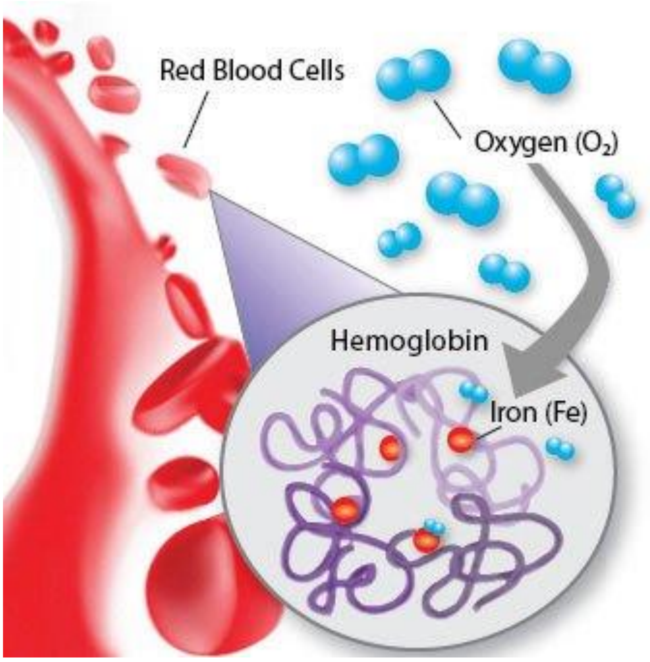


Figure 2. Schematic representation of the oxygen adhered in Hemoglobin (10).

1.3. Pulse Oximeter Operation

The pulse oximeter calculates oxygen saturation and heartbeat through the measurements on the patient's finger. This is a device that performs a non-invasive measurement of oxygen carried by hemoglobin inside the blood vessels. Its operation is based on detecting blood pumps as changes of more or less absorption (11). Pulse oximetry consists of two principles, spectrophotometry and plethysmography.

1.3.1. Spectrophotometry

A spectrophotometer indicates the intensity of the light transmitted through a substance at a certain wavelength. The fraction of light absorbed is represented as the extinction coefficient of the light in the substance. This spectrophotometer is made up of a photodetector, which is capable of converting light intensity into electric current (9)(7).

Now, the measurement of light absorbance in a pulse oximeter is based on the union of two physical laws, Beer's Law and Lambert's Law. Lambert's Law describes the amount of light absorbed is proportional to the length of the path that the light has to travel in the substance it absorbs. Beer's Law explains the amount of light absorbed is proportional to the concentration of the substance that absorbs the light (7).

In definitive, Beer-Lambert's Law explains the attenuation of light traveling through a uniform medium containing an absorbent substance. That is, incident light of an intensity that will cross a medium, part of this light will be transmitted by the medium, the other part of the light will be absorbed. Therefore, as seen in the formula (a), the intensity of light traveling through the medium will decrease exponentially with distance (12).

$$I = I_0 \cdot e^{-\varepsilon(\lambda)\mathrm{cd}} \quad \text{(a)}$$

where:

- $\varepsilon(\lambda)$: extintion coefficient.
- c: concentration of the adsorbed substance (constantin the middle).
- d: distance of the optical path through the medium.

On the other hand, the ratio that is between the transmitted light ((I) and the incident light (I_0) is called the transmittance (T) of the light that passes through a medium with an absorbing substance (12).

$$T = \frac{I}{I_0} \quad \text{(b)}$$

Likewise, the undispersed absorbance (A) during this process is expressed in equation (c) as:

$$A = -\ln(T) \quad \text{(c)}$$

Based on these principles, a pulse oximeter works in such a way that it emits two wavelengths (660 nm and 940 nm) through a medium, in this case, the biological tissue, and then measures the signal of the light that was transmitted through the medium. Taking into account that: the greater the amount of hemoglobin per unit area, the greater the amount of light is absorbed; the emitted light must travel through the artery and the concentration of hemoglobin will depend on the thickness of the artery, and oxyhemoglobin (HbO2) absorbs more infrared radiation than hemoglobin (Hb) (7).

Figure 3 shows the extinction coefficient of the oxyhemoglobin (black curve) and hemoglobin (blue curve) exposed to different wavelengths.

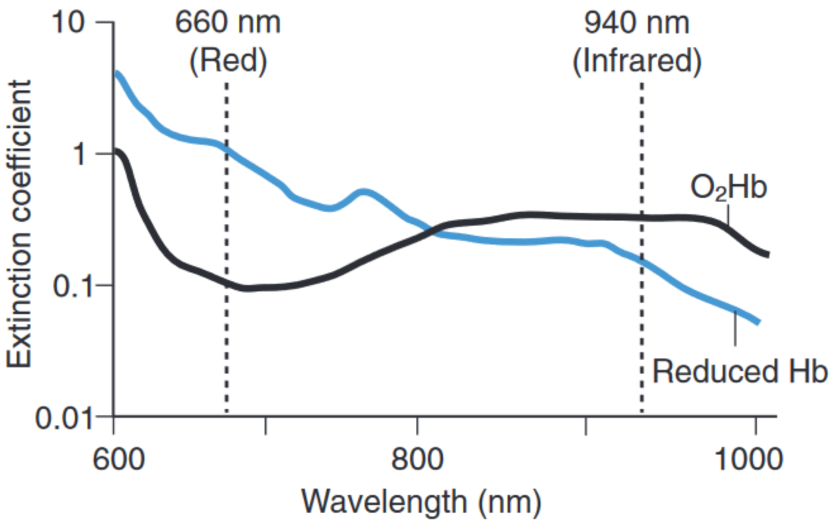


Figure 3. Hemoglobin light spectrum absorption curve (13).

1.3.2. Plethysmography

There are other tissues that can interfere with the measurement of the oximeter since arterial blood is not the only one that absorbs light. As a solution to them, pulse oximeters only occupy arterial blood because it is the only one that has a pulsating absorbance while the other tissues do not have these characteristics (7). The principle in plethysmography is based on the volume of arterial blood and the absorption of light by said volume that varies depending on the arterial pulse. The plethysmography wave (PPG) is generated during a cardiac cycle and is commonly measured at a peripheral site such as the hands or feet. The PPG signal has very important physiological information to control neurological, cardiac, and respiratory parameters (14).

The morphology of the PPG wave is based on events of the cardiac cycle such as blood is expelled from the heart when the left ventricle contracts and propagates along the arterial tree that corresponds to the initial positive slope of a PPG pulse as seen in Figure 4. The maximum of the wave indicates the systolic peak, and the amplitude is corresponding to the closure of the aortic valves or diastole decreases (14).

Consequently, the PPG signal is made up of two main components (Figure 4):

- Static direct current (DC) which represents transmitted light from static arterial blood such as skin, venous blood, and tissues, and
- Alternating current (AC) that indicates the variation that exists in the absorption of light related to the changes in the volume of arterial blood (14).

Changes in light absorption are measured by the photodetector, which allows estimating arterial SpO2 and heart rate.

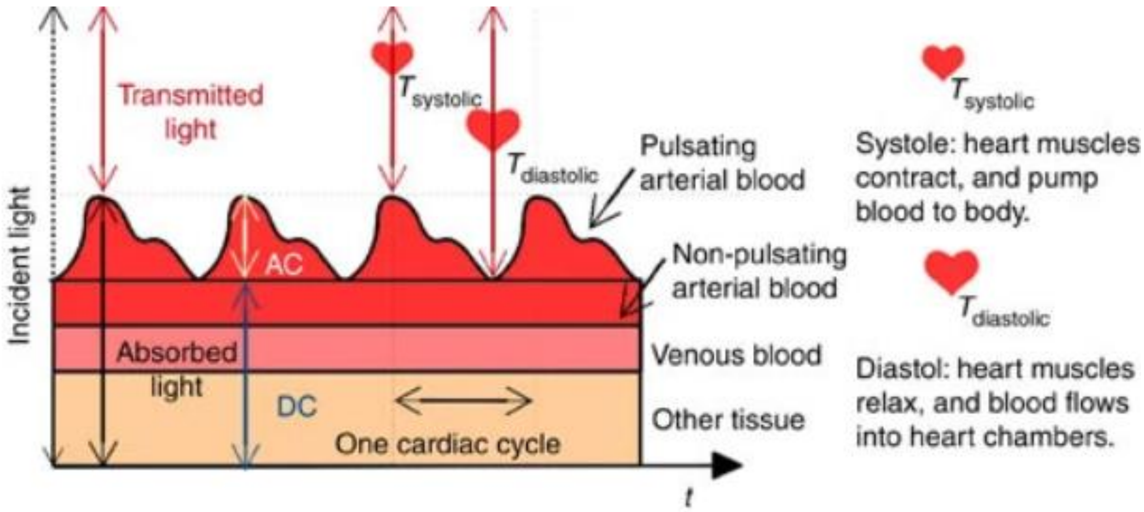


Figure 4. PPG waveform when light is transmitted through a tissue (15).

1.3.3. Pulse oximeter sensor

The pulse oximeter sensor consists of two parts, the light-emitting diodes (LEDs) and a light detector (called a photodetector) (8). On the other hand, there are two ways to measure the sensor's light: transmittance and reflectance (Figure 5). The transmission sensor is positioned so that the LEDs and the photodetector are facing each other (8). This method is the most commonly used and is placed on the fingertips, ear, and foot. Oximeters are used in positions such as the palms of the hands and soles of the feet in newborns and small infants (16).

While in the reflectance sensor, the LEDs and the photodetector are placed next to each other. The measurement is taken from the reflection of the tissues, blood vessels, and bone towards the photodetector. It can be measured in places like the wrist, forearm, ankle, and forehead (13).

In the case of premature babies have to take into account that the skin of prematurity is very fragile so, is it must try to use sensors that protect the skin and preferably that are disposable. It is suggested to have a pulse oximeter in all delivery rooms and be individualized for each patient (17).

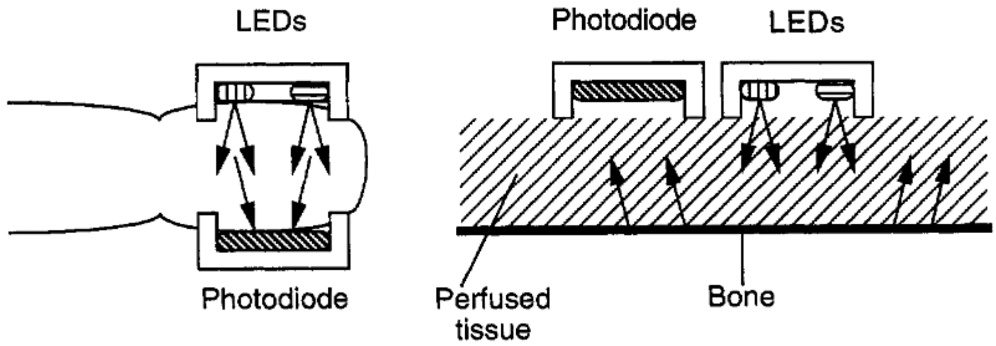


Figure 5. Schematic representation of: method of transmission (left) and method of refraction (right) (12). The transmission sensor is positioned so that the LEDs and the photodetector are facing each other. the reflectance sensor, the LEDs and the photodetector are placed next to each other.

1.3.4. Oxygen Saturation

Oxyhemoglobin saturation (SO2) represents the relative concentration of HbO2 that is bound to oxygen in a given quantity of blood, expressed as a percent of the total concentration of reduced Hb and HbO2. This quantity is commonly referred to as functional oxygen saturation and is defined as oxyhemoglobin and is represented by the equation (d) (18):

$$\text{Oxyhemoglobin Saturation}(\%) = \frac{HbO_2}{Hb + HbO_2} \text{ x } 100 \quad \text{(d)}$$

Therefore, a normalization (scaling) process is usually working in which a photodetector restrains the pulsatile component (alternating current, AC) and the nonpulsatile component (direct current, DC) of the red and infrared PPGs. This process produces a normalized AC/DC ratio for both the red and the infrared PPGs. The ratios of these two normalized AC/DC ratios, mostly independent of the incident light intensity, are denoted by R and are equal to (e) (18):

$$R = \frac{AC_R/DC_R}{AC_{IR}/DC_{IR}} \quad (e)$$

where:

- AC_R: pulsatil red component
- AC_{IR}: pulsatil infrared component
- DC_R: nonpulsatile red component
- DC_{IR}: nonpulsatile infrared component

Pulse oximeters have a microprocessor that uses this ratio to determine the percentage of hemoglobin bound to oxygen (SpO2) (19). The maximums and minimums of the pulsating signal of each of the waves (red light and infrared light) will correspond to the maximum and minimum absorptions (7). SpO2 values were calculated using the next formula (f) (12):

$$SpO_2 = 110 - 25 * R \quad (f)$$

1.3.4.1. Oxygen Saturation Normal Values

Lack of oxygen in the body is called hypoxemia. A healthy individual with normal lungs will have an arterial blood saturation of 95-100%. When the saturation is 90%, the individual may suffer from cyanosis; that is, the individual is desaturated and tend to have a blue color. Also, under 90% indicates low saturation or hypoxemia (15).

SpO2 values lower than 80% elevated to 96% in preterm babies are harmful figures, since it could be associated with retinal vascular lesions (16).

Table 2. Normal levels of Oxygen Saturation (20) *(21)

Age	**Normal Oxygen Saturation**
Premature Babies	89-94% *
Newborn- 2 years	≥95%
2-10 years	≥95%
10 years-Adults	≥95%

1.3.5. Heart Rate

Heart rate means how many times the heart goes through the full cycle of pumping (filling and emptying) blood in a given time. It is expressed as the number of beats per minute, as could see in the formula (g) (22). The peaks of the infrared (IR) signal permit measures the heart rate in a determined time (23). On the pulse oximeter, they are averaged every 5 to 20 seconds (15).

$$Heart\ Rate = \frac{Number\ of\ pulsations}{1\ minute} \quad (g)$$

1.3.5.1. Normal Values of Heart Rate

Normal values are used to know if the heart is beating too fast or too slow. Also, children generally have higher heart rates than adults (20).

Table 3. Normal levels of heart rate (20).

Age	Normal Heart Rate
Premature Babies	100-180
Newborn- 2 years	100-180
2-10 years	60-140
10 years-Adults	50-100

1.4. Oximeter Overview

1.4.1. Pulse oximeter applications in premature babies

The first pulse oximeters were introduced in the United States in 1980. Their first application was in preoperative care (in surgery), but they soon expanded in neonatology, pediatrics, and the intensive care unit (ICUs). Considering the value of continuously monitoring the patient's physiological aspects, many companies began to make copies (24). Since its creation, this device has become a routine part of medical practice and its measurements an essential vital sign in different situations, such as:

- The importance of the pulse oximeter is that it provides an early warning of **hypoxemia** (SpO_2 less than 90%). Based on a randomized trial with 20,000 perioperative patients, results obtained where the incidence rates of hypoxemia were 7.9% when they were monitored, and only 0.4% when they were without an oximeter (52).

- Neonatal care: to monitor hyperoxia in premature infants. Here, the pulse oximeter monitors the amount of oxygen to be administered, and it is recommended to maintain oxygen saturation between 90 percent and 93 percent (25).

- Neonatal resuscitation: it has been justified that oxygen saturation is gradually increased after birth due to increased pulmonary flow and improved pulmonary ventilation (25).

- Screening of congenital heart disease: having a late diagnosis of congenital heart disease could lead to the risk of death or injury in newborns. So far, it is recommended to use pulse oximeter as a screening. In the Netherlands, the prenatal detection rate of Congenital Heart Disease (CCHD) was 73%. Pulse oximeter applied as a protocol in this study was screened, 23 959 newborns (26). Another study where fourteen Norwegian hospitals in the pediatric services and neonatal intensive care do a pulse oximetry screening for infants. The results show that 88% was detected as a Congenital Heart Defect before going home (27). Furthermore, in another research to probe the pulse oximeter, apply a protocol to control the heart problems in a newborn where 50% of patients evaluated was early detection of the disease (28).

- Hypoxemia screening in emergency services: pulse oximeters will have the power to be used in children, prone to pneumonia, bronchiolitis, cyanosis, seizures, or severe dehydration. In a study, was evaluated four pulse oximeters from a different trademark in 10 healthy adults. The results show that all oximeters detected hypoxemia during motion and low perfusion (25).

- Monitoring in the perioperative period: the pulse oximeter as an indispensable requirement in an operating room (25).

- Respiratory diseases: When newborns should be intensively cared for due to pathologies such as pneumonia, asthma, bronchiolitis, and then monitor the development of the treatment, the pulse oximeter is recommended (25). In a study of five days, the treatment of pneumonia due to the duration of hypoxemia can range from hours to several weeks. The children with respiratory pathologies need to be monitored clinically and with pulse oximetry at least twice a day (30).

- Sudden Infant Death Syndrome (SIDS):: A study shows that an infant monitoring system was developed, which is responsible for monitoring the exhaled air of a baby and thus reduce potential risks that can be used to monitor the exhaled air of a baby, in order to reduce the potential risks SIDS (23).

1.4.2. Alarms

In recent years, preterm newborns have increased survival cases, especially those with less than 1,500 g. However, neonatal morbidity (sick babies) increases with some pathologies, such as: in retinopathy of prematurity (ROP), pulmonary dysplasia (BPD), among others (31). The most widely used method for monitoring oxygenation is the pulse oximeter, and its sensitivity depends on various brands. For this reason and to avoid episodes of hypoxemia (low SpO2) and hyperoxia (high SpO2), an oximeter must have an alarm system based on common values (31).

Besides, based on monitoring and control techniques of the pulse oximeter for neonates, it should be taken into account that the sensor should be rotated every 2 or 3 hours because the light could cause burns, choose the appropriate sensor by weight and type of patient (32).

1.4.3. Limitations of the pulse oximeter

Obtaining a significant, valid, and reliable result of the pulse oximeter can be affected by several circumstances:

- The movement. This condition occurs, especially in children or newborns. When there is noise interrupting the only pulsating component in motion that was arterial blood, there will now be moved in the venous blood, and the oximeter could confuse it (25).

- Low perfusion. The vascular bed's perfusion between the two sensors (emitter and photodetector) determines the magnitude of the signal available for the pulse oximeter.

- Electromagnetic interference. External electromagnetic energy, such as cell phones, tomography. These could cause sensor overheating.

- Ambient light interference. The intense white or red light can interfere with the reading of the oximeters (25).

- Other Hemoglobin. As the carboxyhemoglobin that has the same absorbance as Oxyhemoglobin. Methahemoglobin that gives a brown pigmentation to the blood and has an absorbance of 660 nm at 940nm (33).

However, with new technologies, these limitations have been solved in a better way, such as Massive SET technology, which is based on algorithms that create adaptive filters, depending on whether the filter is strong or weak, it varies over time, to control the movement and low perfusion that are the leading causes of noise. Massive brand oximeters are the first in quality in the world, and it is due to the technology they incorporate, such as the Low Noise Optical Probe, LNOP sensors, which have a photodetector hidden in a folding cavity that reduces noise by the ambient light, electrosurgical noise and other movements (21).

1.4.4. Advances of Pulse Oximeter for Neonates

There are some advances in the area of oximetry. Over time, the pulse oximeters improved to satisfy the needs of a premature baby fully. Recent research has developed thin, comfortable, and wireless sensors that reproduce traditional technologies, such as pulse oximeter and electrocardiogram. It is a flexible adhesive sensor and sends the information through an antenna, which omits wires in the intensive care unit (34).

On the other hand, a study focused on creating a wearable sensor that permits to adapt to the movement to the body and allows to measure the respiration thought intercostal muscles with athletic tape (35).

In the industry, there are some brands such as Nellcor and Masimo that have developed new research in pulse oximeters. Masimo has a sensor specifically for cyanotic infants, which has a cable and could be placed on the monitor. It also has cables that connect to the cell phone. All these innovations have high precision but also have high costs (around 250 dollars) (36). Similarly, another KineMax device has a clip sensor that is priced around 115 dollars, the same one that does not have a computer graphic interface (37). Another device, a portable neonatal oximeter saturation with alarms, pulse wave display, clock function, and can send data to computers, is priced at 109 dollars (38).

1.4.5. Normative

Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance, of FDA(Food and Drug Administration) Staff, mentions that the accuracy is related to the patient's characteristics as well as the place of application and the sensor construction. They recommend that the device design be compared to one that is legally on the market (39). Other regulations associated with pulse oximeters are ASTM F1415, ISO 9919 (12).

1.5. Electronic Principles

1.5.1. Signal Acquisition

As we understand the operation of a pulse oximeter, it is necessary to be clear about the electronic part of this device.

1.5.1.1. LED

An LED (light-emitting diode) is an optoelectronic semiconductor diode that produces light by electroluminescence. It stands out for its high light emission efficiency compared to other methods. Its input voltage range for its operation is 0.9 to 2.5 V (12).

1.5.1.2. Photodetector

A photodetector is a sensor that produces current which is linearly proportional to the intensity of the light incident on it (12). The oximeters take into consideration important aspects for the photodetector, such as the linearity of the intensity of the incident light or illumination, the sensitivity or the ratio of the electrical output signal before the incident light, and the size. In fact, there are different photodetectors: photocells, photodiodes, phototransistors. There are two very important interferences that cause problems to detect light by the photodetector: excessive ambient light and when the LEDs are too close, confusing the photodetector (12).

1.5.2. Signal Processing

Based on the action of the photodetector, it generates a proportional current to the intensity of light. This current is converted into a voltage by an analog amplifier. Indeed, it was found that the change in the voltage (due to the pulsations of the arteries) is very small in comparison with the DC component of the signal. In this case, this DC component must be removed. Since the AC component of the signal brings with electromagnetic interference and high-frequency noise, low pass filters are applied (12).

Then each signal arrives at the microcontroller (Arduino), which has the function of converting the signal from analog to digital (ADC). PIC micro-controllers operate in a range from 0 to 5V (40).

Hence, the signal must go through a process of amplification and filtering. Taking into account that, the frequency band of the pulse wave of the pulse oximeter is in a range of 0.5 to 4 Hz, the frequency band of noise related to movement (trembling of the fingers, movement of the fingers, etc.) is 0.1 Hz or more (41). One or more filters must be used (analog, digital, or both) to filter out the noise and other unwanted signal components (42). Below show some of the filters used:

- Low-Pass Filter (LPF). It allows low frequencies to pass and limits high frequencies.
- High-Pass Filter (HPF). It allows us to pass high frequencies and blocks low frequencies.
- Bandpass Filter (BPF). It lets through frequencies that are within a frequency range and blocks out wings.
- Operational Amplificator (OP-AMP). It is an electronic unit that behaves like a voltage-controlled voltage source. It has the ability to add signals, amplify signals, integrate or differentiate it when external components such as resistors and capacitors are connected to its terminals (43).

1.6. Graphic Interface Principles

Health personnel needs to monitor the patient in order to make a diagnosis (44). Indeed, information technology, electronic devices, and telecommunications allow the development of applications with characteristics such as recording, storage, and monitoring of physiological signals from patients (45). There are several programming languages to create these applications. In this case, Python was used.

1.6.1. Python

Python is a high-level programming language that allows people to build programs. It has the following characteristics: it is easy to learn, is free software, is developed under an open-source license, and has libraries, among others (46).

2. PROBLEM STATEMENT

According to the WHO (World Health Organization), 15 million babies are born too soon every year. More specifically, 1 in 10 babies is born prematurely. The conditions of premature birth result in the second leading cause of death in newborns after pneumonia in children under five years of age, and the worrying thing is that the figures will continue to increase (2) (Figure 6 and Figure 7).

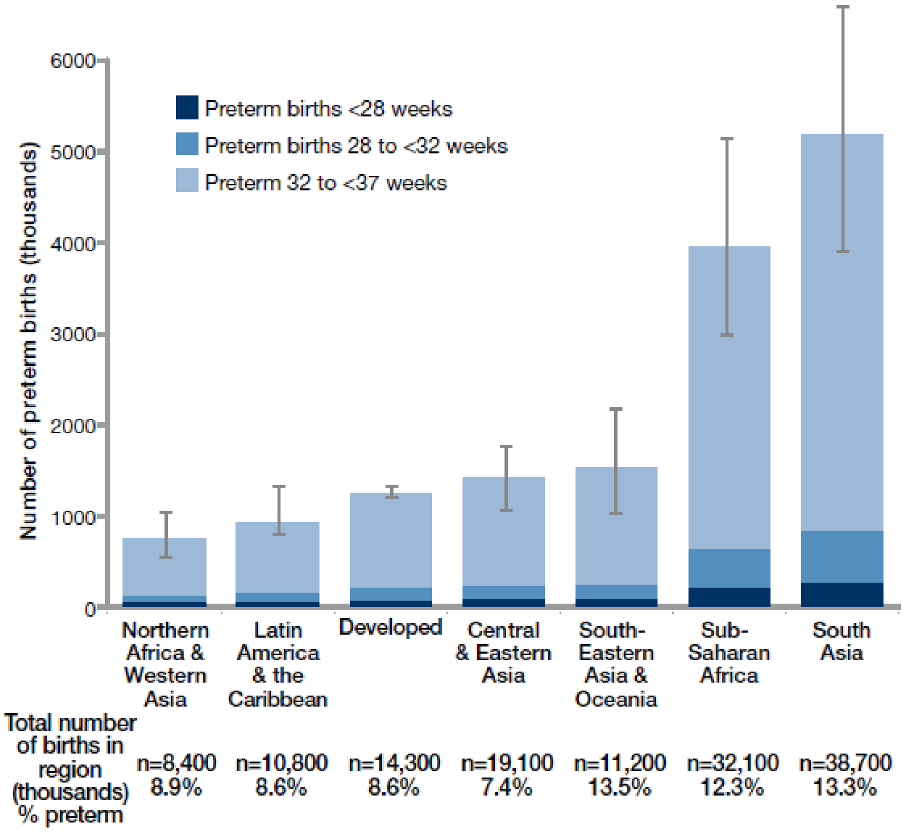


Figure 6. Preterm births by gestational age and region for year 2010 (47).

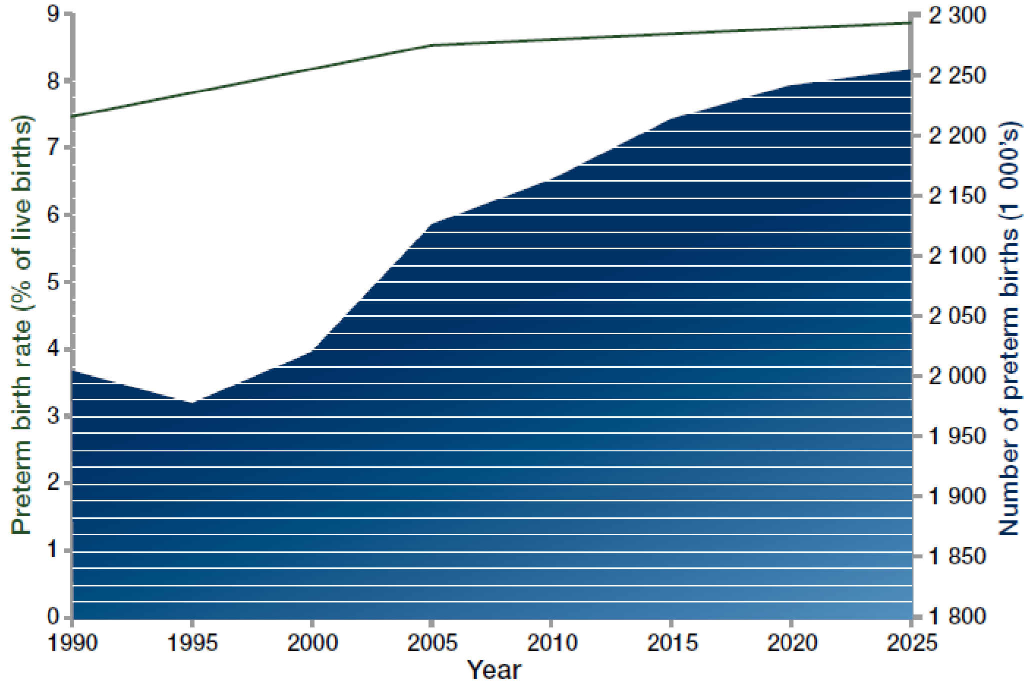


Figure 7. Time trends in preterm birth rate for regions with adequate data (47).

In Latin America, the statistics of the infant mortality rate in children under five by complications of premature birth are the following: Costa Rica and Chile, 27.2 and 27.1 percent, followed by Argentina and Venezuela with 26.0 and 24.6 percent respectively. Ecuador has a mortality rate of 19.7 percent. It means that 5.1 out of every 100 births are prematurely born children (48).

Premature babies are more prone to chronic diseases or death during their neonatal period. If they do not have proper control and treatment, they are at risk of dying, having a permanent disability, and a poor quality of life (50). On the other hand, it has a negative impact on the health systems and finances of a country due to the cost of assisting a premature baby. A small premature child costs ten times more than a term baby and potentially conditions permanent sequelae (50).

Extremely premature babies must enter the Neonatal Intensive Care Unit (NICU), where they are frequently incubated and have constant monitoring of their weight, breathing, and in some cases receive oxygen therapy. After babies are discharged, they should continue to be controlled in their homes, through vaccines or neonatal services, which can cause anxiety in mothers (1).

Breathing in a premature baby is one of the most important vital signs since most diseases or syndromes are related to breathing. There are other signs such as temperature, weight, and behavior that are valued by the doctor. In this case, the present work will focus on the pulse oximeter device used in all pediatric and neonatal units with the function of measuring blood oxygen saturation through physical and electronic methods (24).

2.1. General Objective

To create a prototype pulse oximeter, which is adapted to premature babies and detect health problems related with oxygen saturation.

2.2. Specific Objectives

- To use the electronic and programming tools to achieve measure oxygen saturation and hear rate.
- To design a device that sends alerts to detect some a normal measure, has a low cost and uses wireless technology.
- To create an interface to save the received data of the hardware to posterior analysis.

3. MATERIALS AND METHODS:

The system developed in this project is made up of two parts: Software and Hardware.

The hardware stage is, in turn, formed of three steps:

1. To make a signal acquisition,
2. To make a signal processing, and
3. To make a calculation performed by a microcontroller.

The software consists of an application, which has two main functions:

1. To calculate the oxygen saturation and heart rate with the data acquired from the hardware in real time
2. To store in a database both the medical history of the patient and the calculated data.

The whole system is shown in Figure 8.

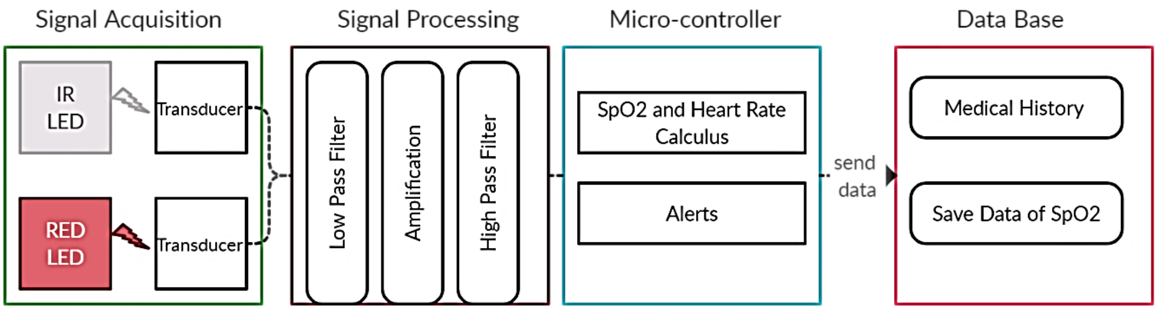


Figure 8. Electronic circuit and data base (Hardware and software) in block diagram.

On the other hand, Figure 9 shows the entire development of the project in a functional way. The electronic device connected to the premature baby, the same that consists of alarms and sends the data to the computer via Bluetooth.

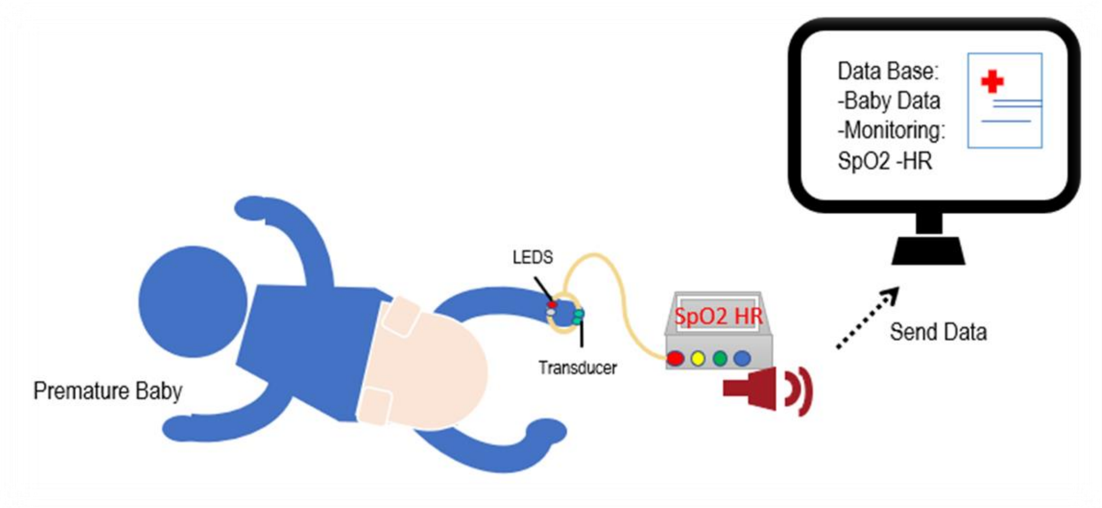


Figure 9.-Prototype project, hardware and software summary.

3.1. Hardware

3.1.1. Signal Acquisition

In order to acquire the signal, the design uses two LEDs, an infrared LED and a high brightness red LED, which emit and receive light through the skin tissue. The wavelength of the infrared LED is 940 nm, and the red LED is 660 nm. The light is received by two phototransistors, which have an input voltage of 1.3 V. Also, and the photodiode assembly should be protected from ambient light in the wavelength range in which the photodiode is sensitive. For this reason, a 5 cm x 4 cm box was designed for performance tests in which only the LEDs are connected. Similarly, the sensor was tested on a person's finger (Figure 10). On the other hand, the power supply to the LEDs is 5 volts from the Arduino.

Table 4. Voltage input resistance test to LEDs. The boxes marked indicate the resistors that was used for the acquisition of the signal.

Resistance	Red Led	IR LED
220 ohms		X
160 ohms		
147 ohms	X	
47 ohms		

In addition, it was tested with several resistance values (Table 4), to verify the proper current flow through the emitting led without burning it and at the same time provide enough light intensity to be detected by the phototransistor. The high brightness red led has a threshold voltage of 1.9 V while the infrared led has 1.7 V. The values obtained (220 ohms for IR led and 147 ohms for Red led) with the resistances used are within the voltage limits.

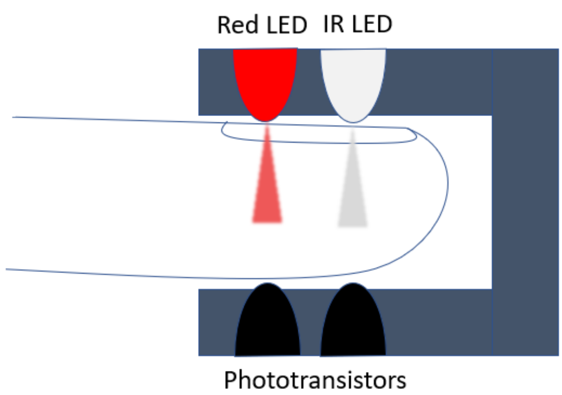


Figure 10. Schematic representation of position of the LEDs and phototransistors.

3.1.2. Signal Processing

The signal waveform of the plethysmography frequency is in the range of 0.5 to 15 Hz. Several tests were performed with different cutoff frequencies to set up a band-pass filter that encompasses the pulsed wave range, and the signal graphs were checked on Arduino's serial plotter. To obtain the cutoff frequencies, the following formulas were applied (d) for low-pass filter and high-pass filter cutoff frequency, while the gain was that of a non-inverting amplifier (e):

$$f_C = \frac{1}{2\pi RC} \quad (d)$$

where fc: cutoff frequency, R: resistance and C: capacitor

$$A = 1 + \frac{R_2}{R_1} \quad (e)$$

where A: gain, R: resistance

Testing began with 10.6, 8, 4, 3.3, and 3 Hz for the low-pass filter, while the high-pass filter the cut-off frequencies were 0.5, 0.6 and 1.5 Hz. Finally, a band-pass filter configuration was chosen, consisting of a low-pass filter with a 3.3 Hz cut-off frequency and a high-pass filter with a 0.6. The gain is 1000 because the enter pulse wave is not verified, is approximately in the range of 0.001 V Table 5.

*Table 5. Low Pass Filter and High Pass Filter Test along with the cut-off frequencies used. *Means the cut-off and boost frequencies chosen in this project.*

<table>
<tr><th></th><th>Low Pass Filter</th><th>High Pass Filter</th><th colspan="2">Amplification</th></tr>
<tr><td rowspan="6">Cutoff frequency (Hz)</td><td>10.6</td><td>0.5</td><td rowspan="6">Gain</td><td>1000</td></tr>
<tr><td>8</td><td>1.5</td><td>1000</td></tr>
<tr><td>4</td><td>0.5</td><td>1000</td></tr>
<tr><td>4</td><td>0.6</td><td>1000</td></tr>
<tr><td>3.3*</td><td>0.6*</td><td>1000*</td></tr>
<tr><td>3</td><td>0.6</td><td>1000</td></tr>
</table>

3.2.3. Microcontroller

The microcontroller used is Arduino Nano (see Figure 11). Arduino is an open-source electronics platform with effortless functionality. It allows sending instructions to the microcontroller on the board, using Arduino (programming language) and Arduino Software (IDE). Arduino Nano, which has the following specifications, is a small board based on the Atmega328, works with a USB Mini- B cable, operates on 5 V voltage (40).

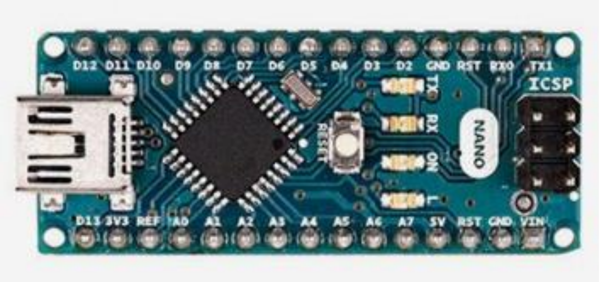


Figure 11. Arduino Nano board (40).

In Arduino's programming, a code was created to calculate the oxygen saturation, the heart rate, and to emit alarms based on important values for proper monitoring.

3.2.4. Heart Rate Oxygen Saturation Calculation

For the calculation of the oxygen saturation was programmed based on the input signal after signal processing, this signal is in a range of 0 to 5 V. As mentioned above it is necessary to obtain the peaks and valleys of the incoming pulsed signal in order to apply the formulas for oxygen saturation.

Similarly, the formula of pulses per minute was applied to obtain the heart rate. In this case, the calculation is made with a time of 15 seconds since the number of AC pulse signals in that time is taken.

In addition, the device has a 16X2 LCD display that is programmed in Arduino to display the oxygen saturation and heart rate values. The 16 x2 LCD display has an operating voltage of 4.7 to 5.3 V, can print 16 characters, can work with 8-bits and 4-bits mode, is inexpensive, and easy to program. On the other hand, the Bluetooth module HC-05 was used to send the data to the computer.

3.2.5. Alerts

The alarms, as mentioned above, are very important to allow to warn the alert situations that the patient may be going through. It joined the circuit colored LEDs (Red, Yellow, and Blue). Red means that the oxygen saturation is under Yellow's traditional values when it is above the average values and blue, which takes the program to indicate the heart rate. Besides, a passive buzzer (51) was adapted to the circuit, an electro-acoustic transducer that emits a sound when faced with various instructions. In the following table, Table 6, can see how each of these alarms was programmed.

Table 6. Configuration of the alarms in the electronic circuit.

	Premature $SpO_2 < 86\%$	**Premature $SpO_2 > 96\%$**	**System Initiation (15 seconds)**
Red Led	X		
Yellow Led		X	
Blue Led			X
Buzzer ☺	X	X	

3.3. Software of Graphic Interface

In the implementation of a database, it was designed a graphic interface with Python programming language. Software that can be downloaded for the computer from the Python.org website (53). Then it starts with the algorithm programming of the application of this pulse oximeter device. This interface consists of several windows that allow us to create a user account to verify whether it was already registered before.

After entering the system, it allows us to make two options: Fill in a medical record of the baby, data that will be saved in a database in the ".txt" format. The second option is to monitor both the oxygen saturation and the heart rate in real-time for a determined time that the user requires. This data is received from the hardware and saved in an Excel book (from Microsoft) for later diagnosis.

The programming commands are summarized in the following flow chart, Figure 12.

3.4. Function Test

It was tested in three subjects (adults aged 23, 42 and 45 years) at rest and, compared with a commercial device Vitalcontrol SPO25, in order to verify that the operating principle of the pulse oximeter, that is, the measurement of the oxygen saturation and heart rate.

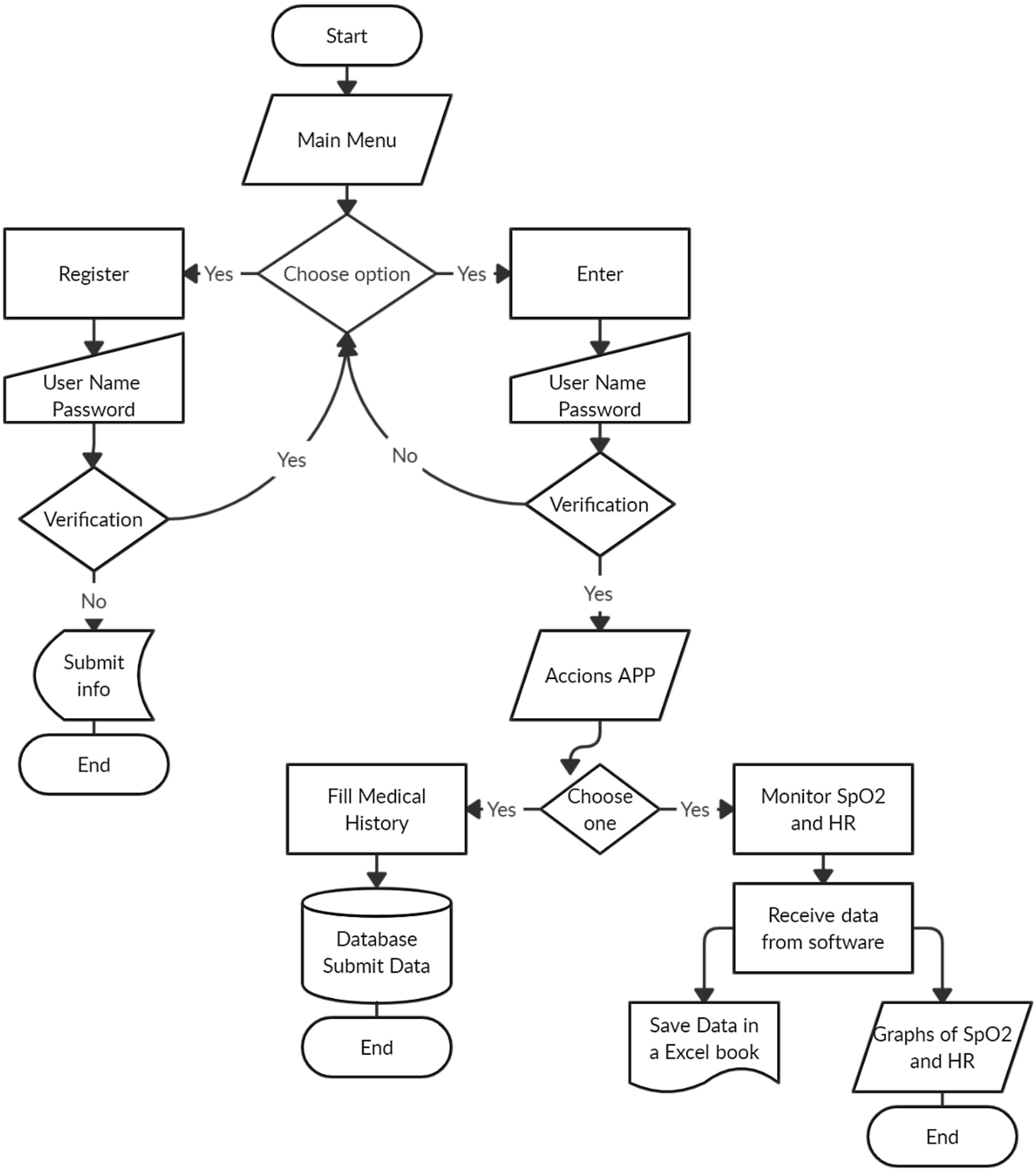


Figure 12. Flow chart of graphic interface.

4. RESULTS, INTERPRETATION AND DISCUSSION

According to the methodology that was performed can be viewed at the top of Figure 13a, the signal received by the Arduino microcontroller when connected to the computer. The results of the graphs were obtained with the Python program connected to the Arduino microcontroller that contains the created circuit. The signal is obtained when red led is continuously ON, and the finger is placed between the red led and the phototransistor. It is observed that the voltage received is between a range of 1.4 to 1.8 V, i.e., 0.1 and 0.2 V, and still, the pulse wave is not verified. It was obtained that the voltage of the input signal is between 0.001 V. For this reason, the second graph of the signal in Figure 13b shows the signal obtained by the photodetector of the red led amplified and filtered. It can be seen that the voltage received is now between 0 and 2 V, thanks to the applied amplification of 1000 gain, and the AC component (pulsed part) and the DC component (continuous part) are verified.

In this way, it is possible to display the digital signal in Arduino since this microprocessor allows a range of 0 to 5 V. Also, the signal applied a low-pass filter of 3.3 Hz, which allows eliminating the noise from the signal, taking into account that the range in which the pulse wave is located in between 0.6 Hz and 15 Hz.

However, as it can be seen, low-frequency noise can be produced by the finger movement that makes the signal valleys undetectable. Therefore, to solve this problem in the lower graph of Figure 13c, the signal applied a high-pass filter of 0.6 Hz, which is clean, without noise, and ready for analysis.

Similarly, in Figure 14, the signal processing for the signal obtained by the infrared LED phototransistor was performed. It is observed at the top of the original signal input to the microprocessor, which is in a range of 0.2 to 0.3 V. Then, the signal is amplified 1000 times, and the voltage received is between 1 and 3 V.

Also, a low-pass filter with a cut-off frequency of 3.3 Hz is applied, which eliminates the high frequencies but keeps the low frequencies. Therefore, the lower graph in Figure 14 shows the pulsed signal applied a high-pass filter with a cut-off frequency of 0.6 Hz. The result is a signal without noise and clean to be used by the microcontroller.

Figure 15 shows the PPG waves obtained from the two LEDs and the components that allow the calculation of oxygen saturation. It can saw the AC pulsed arterial component and DC static component formed by tissues. These waves are in the voltage range. In addition to the infrared light wave, the heart rate is also calculated. In this case, the microcontroller will count the ACs in 15 seconds.

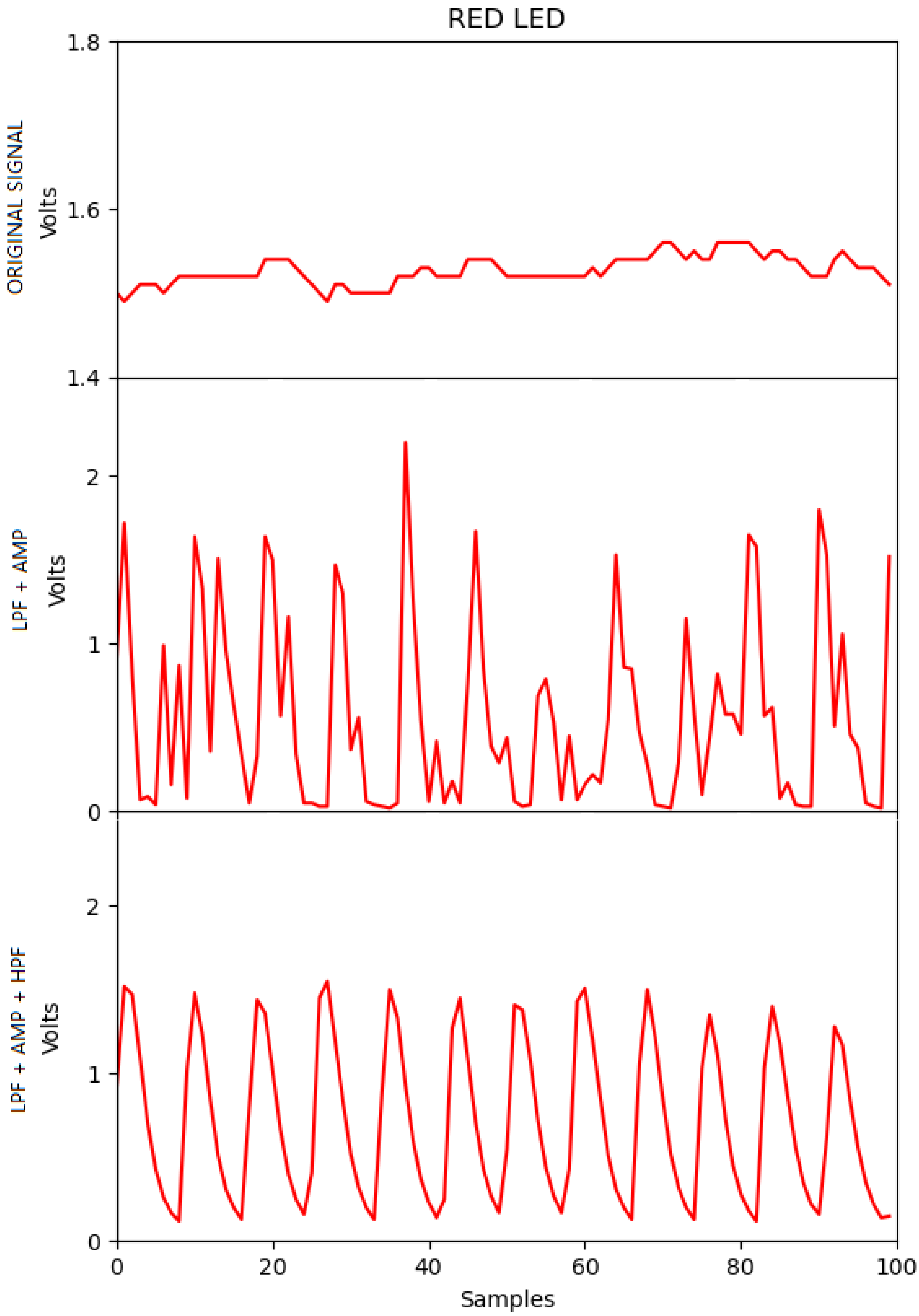


Figure 13.Input signal processing led Red LPF (Low Pass Filter), AMP(Amplification), HPF (High Pass Filter)

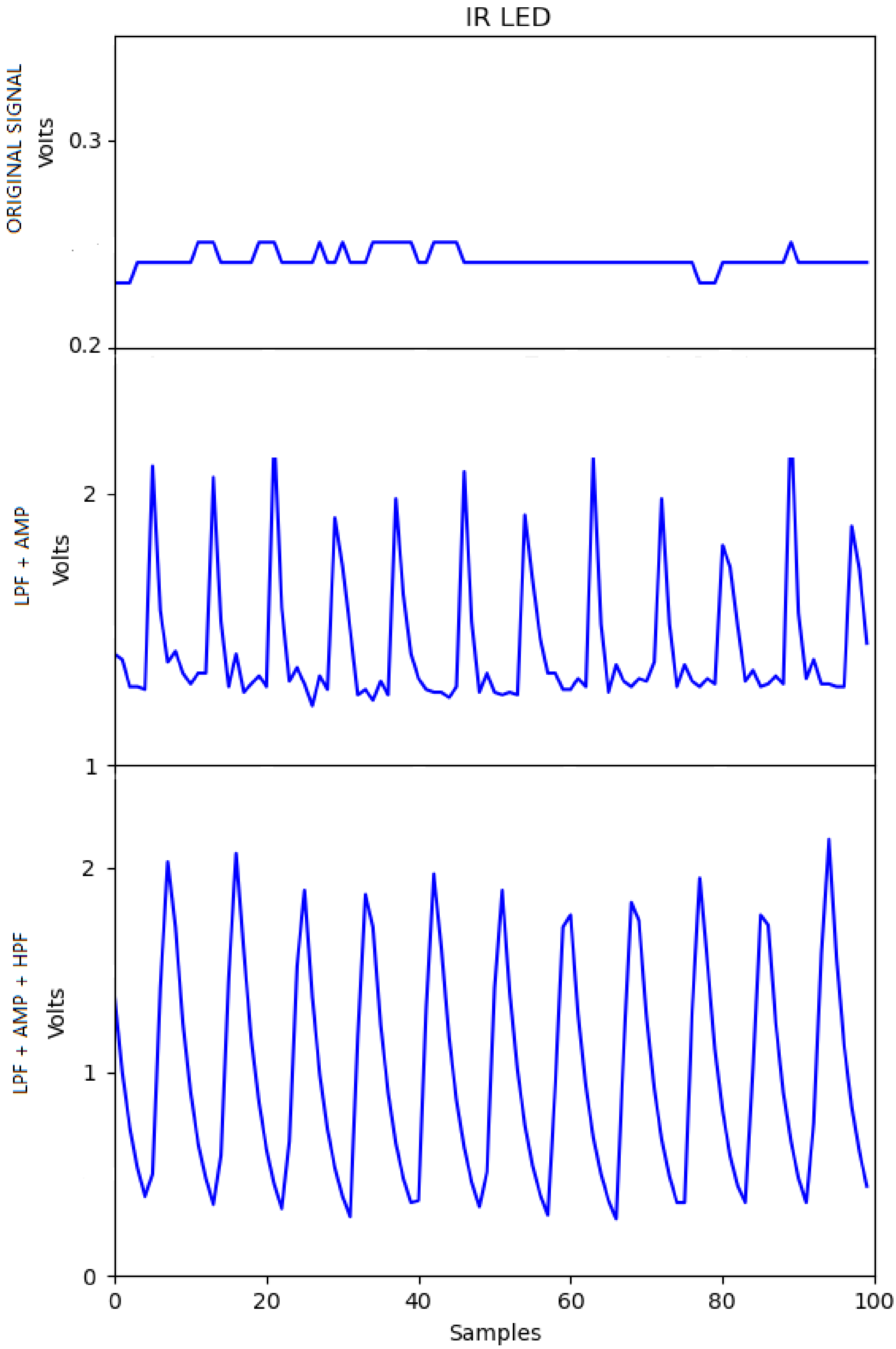


Figure 14.Input signal processing led IR LPF (Low Pass Filter), AMP(Amplification), HPF (High Pass Filter)

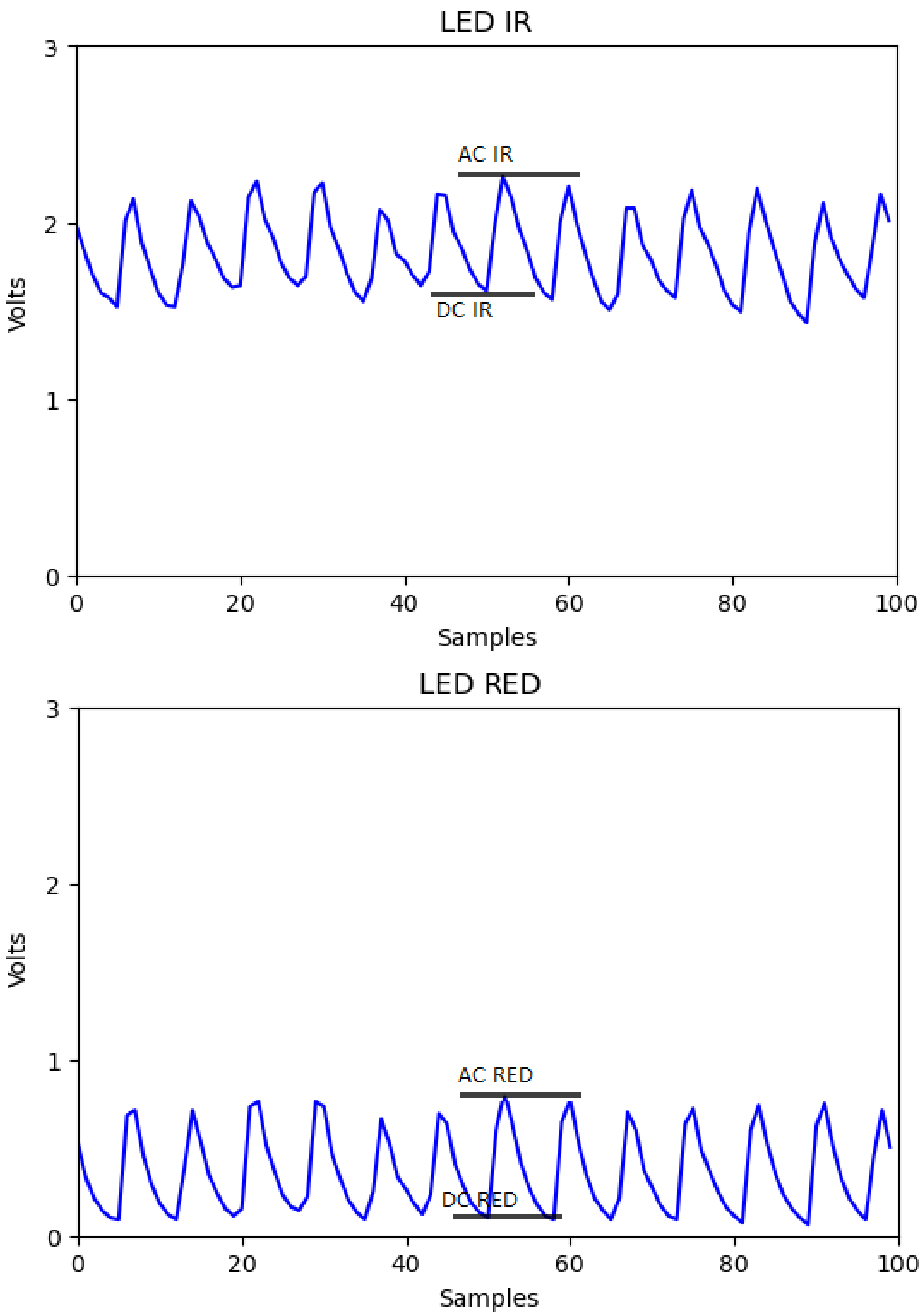


Figure 15.A waveform of the transmitted light intensity through a finger.

Figure 16 shows the first window that corresponds to the login and registration buttons which allows you to create a user account. It takes into account what is important to preserve the privacy of users. Also, based on these data are saved in a ".txt" file on the computer.

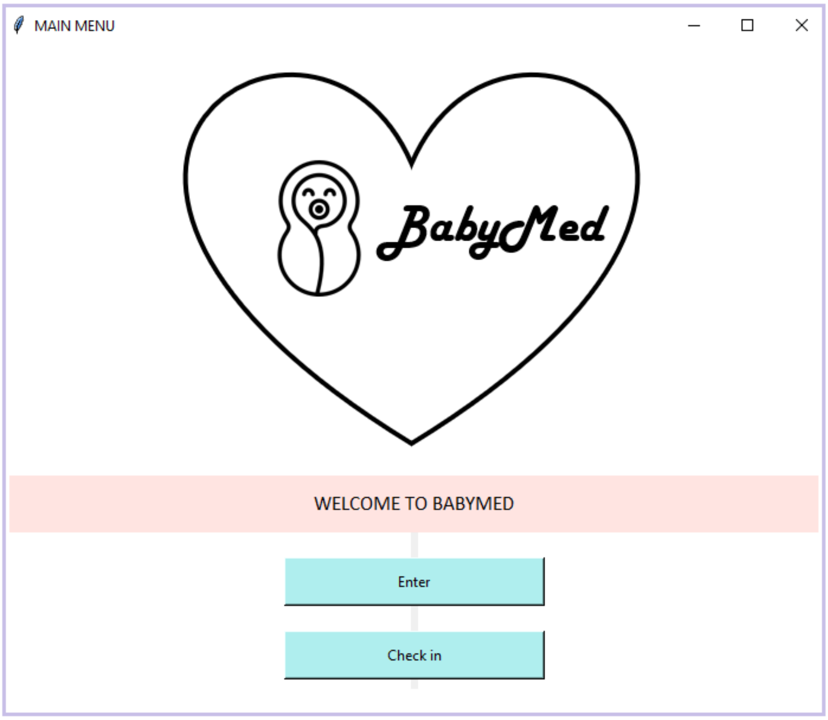


Figure 16. Main entry window to the database and monitoring application.

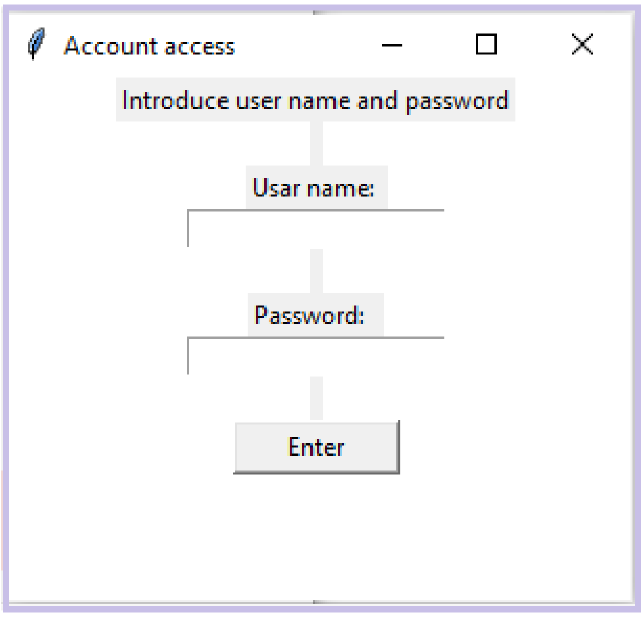


Figure 17.User and password input window.

The second window (see Figure 17) indicates that the user name and password must be entered. Then, in the third window (in Figure 18) of the application allows us to perform two main functions that achieve the objectives of a database: to fill the patient's medical record (in

Figure 19). The next button is related to monitoring oxygen saturation and heart rate to take real-time data of oxygen saturation and heart rate from the electronic device.

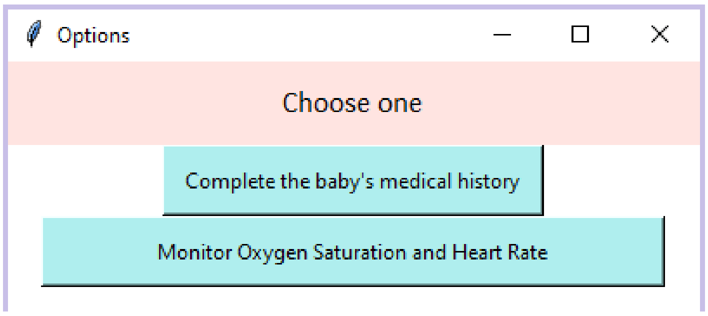


Figure 18. Application actions window.

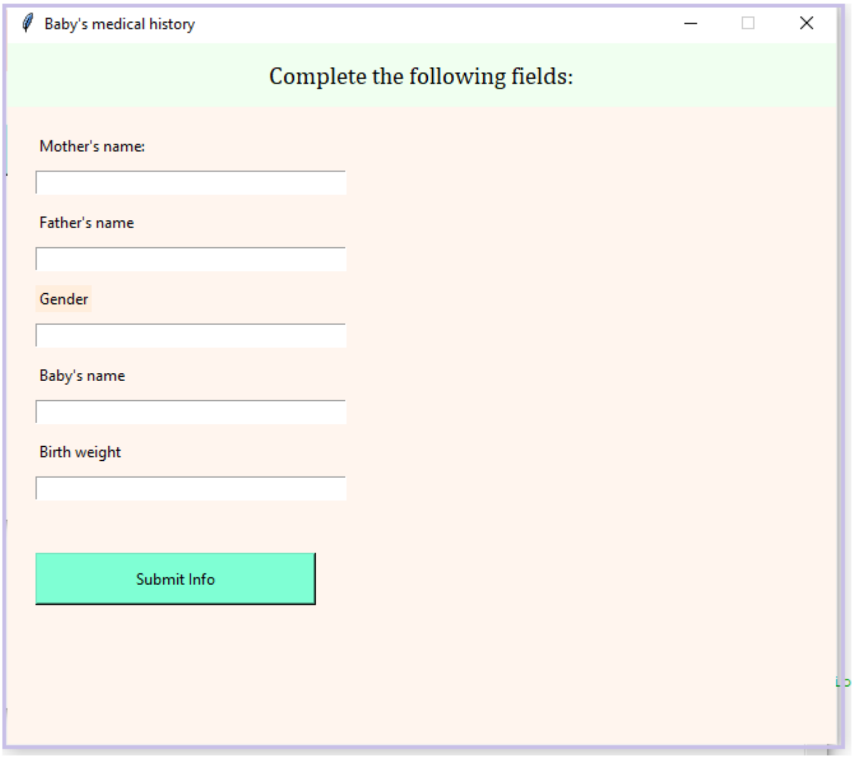


Figure 19.Window where the user fills out the medical form.

Two graphs are instantly generated (see Figure 20) obtained from the software with the monitoring data for 20 seconds. The first 15 seconds of initialization is required, and then the respective values of saturation and heart rate are displayed. Heart rate between values from 60 to 100. Oxygen saturation between values from 85 to 100%. These data were obtained from the created software.

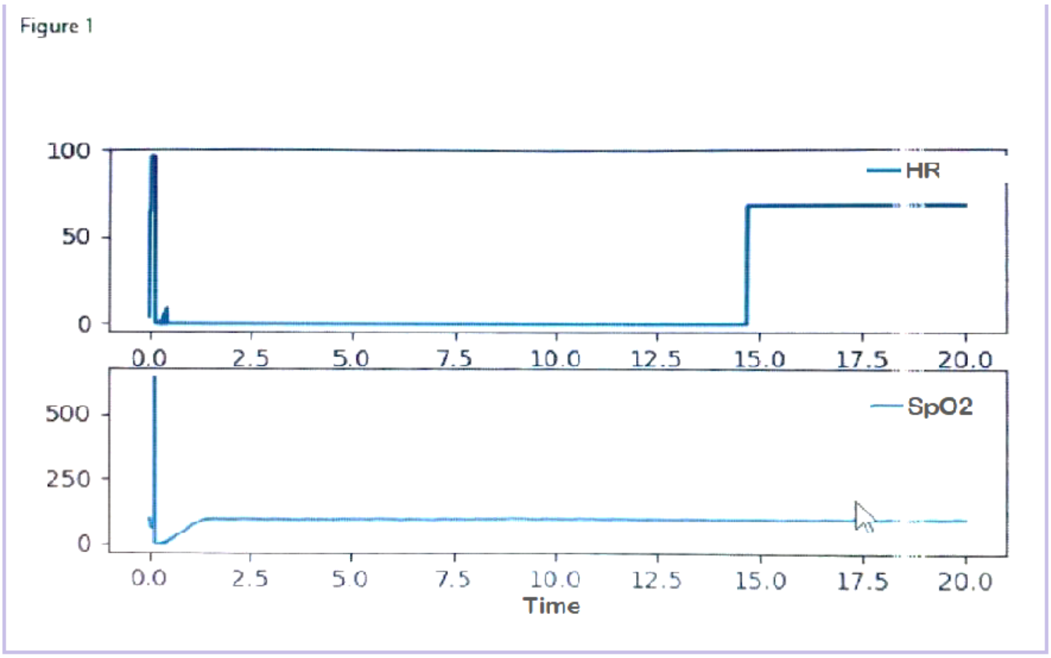
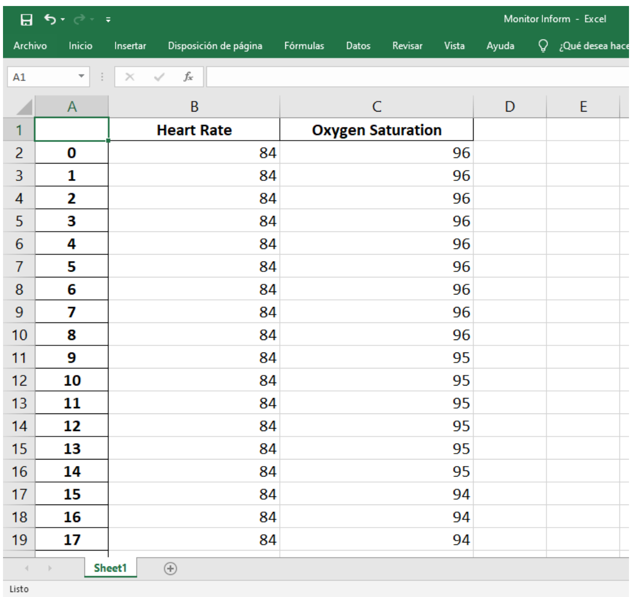


Figure 20. Window where SpO2 and RH graphs are shown for 20 seconds.

Figure 21 shows how the Oxygen Saturation and Heart Rate data will be stored in the Excel workbook. Saving a backup of the data that is being received from the software allows for a future diagnosis of the patient.



	Heart Rate	Oxygen Saturation
0	84	96
1	84	96
2	84	96
3	84	96
4	84	96
5	84	96
6	84	96
7	84	96
8	84	96
9	84	95
10	84	95
11	84	95
12	84	95
13	84	95
14	84	95
15	84	94
16	84	94
17	84	94

Figure 21. Database saved in Excel of the first 17 data

Table 7 compares the obtained results of oxygen saturation and heart rate between a commercial oximeter and the measurements of the pulse oximeter created in this project. Four samples are taken from 3 subjects.

Besides, each of the samples' relative error was calculated, and then an average of the relative error was obtained. The result was an error of 2.1% for oxygen saturation and a 2% error for heart rate. According to the validation of the pulse oximeter, depending on the manufacturer, generally, these devices tend to have an approximate error of 3%, which means that the method used in this project is not so far from a suitable measurement. Furthermore, possibly the errors obtained may be due to some general limitations with the oximeters as movement, finger position, and pressure on the LEDs

Table 7.Trial-error calibration with pulse oximeter on the adult market.

Subjects	**This project**		**Commercial device**		**Relative Error**	**Relative Error**
	SpO_2	**Heart Rate**	**SpO_2**	**Heart Rate**	**SpO_2**	**HR**
Subject 1	96	84	94	85	2%	1%
	92	80	95	76	3%	4%
	92	80	93	80	1%	0%
	94	86	95	85	1%	1%
Subject 2	93	75	90	72	2%	3%
	94	75	90	73	4%	2%
	90	80	94	83	4%	3%
	93	84	93	80	0%	5%
Subject 3	99	72	95	72	4%	0%
	94	72	95	70	1%	2%
	91	68	94	66	3%	2%
	94	68	94	69	0%	1%
	Relative Error Average				2.1%	2%

A summary of material costs is given in Table 8 to verify when the device's total value was (around 36 dollars). As can see, the value is relatively low because the devices on the market that are designed specifically for premature babies are over $90 (36) and do not have an application to save the monitoring data. This calculation gives an idea of the advantage of both the economic side and the baby's constant care side. It is considering that premature babies need to be closely monitored due to the health complications related to oxygen saturation and the diagnoses that must be made periodically.

Table 8. Device proforma

Materials	**Cost**
IR LED	$0.50
High brightness LED	$0.15
Colored LEDs	$0.40
Phototransistors	$4.60
Capacitors	$0.40
Operational amplifier	$0.60
Arduino Nano	$9.50
16x2 LCD	$5.25
Wires and resistors	$1.00
Buzzer	$1.00
Proto-board	$3.00
Bluetooth HC-05	$10.00
Total:	**$36.4**

Table 9 contains the comparison of this project (BabyMed) with other pulse oximetry studies. In the first instance, each research's characteristics are compared, and it is concluded that they all measure oxygen saturation and heart rate. However, a project has an accuracy of 6 percent, outside the allowed error range. BabyMed and the others are within the allowed error range.

On the other hand, some studies are based on the measurement only in adult patients by default, their alert notifications will be for this type of person, while BabyMed can be specific for premature babies with health problems such as hypoxemia (SpO2 minus 90%). Some projects do not have this feature for the computer app, and neither does a record of the baby's medical history.

Besides, the cutoff frequencies that each project used in their creation of the device were compared. It follows that only one project is for wireless communication, but it is intended for adults. Another device measures vital signs in children with sudden death syndrome in the form of a glove, but not for premature babies. On the other hand, the low cost is an abundant feature.

Overall, BabyMed is a complete device and aims to achieve quality, safety, convenience, and easy access for its target consumer.

Table 9.Comparison with other works. Prepared by author.

Tittle	**Description and Qualities**	**Cutoff frequency (Hz)**	**Accuracy**	**Ref.**
This project (Baby Med: Pulse oximeter for premature babies)	The use is destinate for premature babies with health problems related to breathing like hypoxemia. Measure oxygen saturation and heart rate. Alarms Software to diagnostic. Register of Medical History Low cost	0.6-3.3	SpO2: 2.1%, HR: 2 %	Author of this project
Real-time oximetry telemonitoring system OXYS	Adult pulse oximeter, self-calibration, graphical interface, data storage, wireless communication, measurement report.	0.5-20	-	(45)
Telemedicine system for continuous monitoring of vital signs in younger infants avoid sudden death syndrome	Pulse oximeter glove for continuous monitoring for babies with sudden death syndrome. cardiac. It has a mobile application.	-	SpO2: 0.57, HR: 0,93	(54)
Design and construction of a pulse oximeter.	Low-cost pulse oximeter prototype measures oxygen saturation and heart rate in adults testing	Center frequency 1,75	SpO2: 2,06%, HR: 3,57%.	(7)

Design and implementation of a pulse oximeter	Device measure pulse rate, oxygen saturation. Use Arduino.	-	Accuracy differs in ±6.	(55)
Low cost pulse oximeter using Arduino	Design and construction of prototype o pulse oximeter, measure heart rate and SpO2.	1 a 3	-	(56)
Design a non-invasive pulse oximeter device	Use a microcontroller Pic	0.5 a 10	SpO2: 1.5 %, HR: 2.2%	(57)
Design and development of pulse oximeter	Low cost	-	SpO2: 2%, HR: 3%	(58)
Infant Neonatal pulse oximeter Sensor	Patent of pulse oximeter sensor that is applied to the shape of the baby's heel, uses a detector and an emitter.	-	-	(59)
Design of filter to reject motion artifact of pulse oximetry	A pulse oximeter that measures the oxygen saturation in blood. With a filter that reject the movement.	Near to pulse frequency band	-	(41)

5. CONCLUSIONS AND RECOMMENDATIONS

A biomedical device was developed which measures oxygen saturation and heart rate, based on pulse oximetry and spectrophotometry methods, to detect health problems in premature babies through sound and light alarms. Besides, this device acquires the signal through the transmission method (LEDs versus photodetectors), which is generally used in pulse oximeters. It also has the advantage of being portable, easier to use, and mothers do not have problems with cables when carrying the baby.

On the other hand, it is built with low-cost materials, which allows access to people with low income. Likewise, this device saves the medical history and the data monitored in real-time by the electronic part to create a database that allows the mother to keep track of the baby's health so that the family doctor can make a diagnosis of the patient's progress.

It is worth mentioning that a prototype of the device was made, however due to the pandemic it is planned in the future to take this device to the hospital to perform the respective tests on premature babies. In the same way, functional tests would be carried out on babies considering the respective and permitted biosafety tests.

In the future, the prototype for a premature baby would be implemented, taking into account skin sensitivity, duration of exposure to infrared light, and a bracelet for the baby's foot. Also, telemedicine would be adapted, meaning that the device would be working from home and, at the same time, sending the data to the health center so that the personnel in charge could check the baby's condition and act more quickly.

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7. ANNEXES

mundo Electrónico

RUC: 1000849370001

Dir.: Velasco 8-73 y Sánchez y Cifuentes Telf.: 062609896

PROFORMA

Ibarra, 27/08/2020

PARA: Andrea Valenzuela

Cantidad	Descripción	V. Unitario	V. Total
1	led Rojo de alta luminosidad 5mm	0.15	0.15
1	led IR	0.50	0.50
2	fototransistores 5 mm receptor IR negro	2.30	4.60
16	resistencias	0.05	0.80
4	capacitores (10 uf, 1uf)	0.10	0.40
4	leds de varios colores	0.10	0.40
1	zumbador(buzzer) pasivo 5V	1.00	1.00
1	amplificador operacional LM358	0.60	0.60
1	arduino nano V3 ATmega328	9.50	9.50
1	LCD 16x2	5.25	5.25
1	protoboard	4.50	4.50
1	Bluetooh HC-05	10.00	10.00
1	Batería de 9v	2.50	2.50
1	Cable conector de batería	0.25	0.25
	PRECIOS UNITARIOS INCLUYEN IVA	SUBTOTAL	36.12
		IVA	4.33
		TOTAL	40.45

Diana Plasencia

Administradora

CI.1003453923

Venta al por mayor y menor de Equipos de Amplificación, Instrumentos Musicales, Iluminación, Repuestos de Electrónica, Tecnología, Sistemas de Seguridad