Design of Pulse Oximeter with WiFi connectivity and interoperability with standard HL7 and IEEE 11073-10404:2008 (extended version)

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ABSTRACT

Given that health is so relevant for global productivity and competitiveness, and that the Information and Communications Technology (ICTs) play an important role in all of the productivity factors, this work makes use of the ICTs in health matters proposing the to use a WiFi oximeter. This article describes the operating principles of a Pulse Oximeter (PO) which is an opto-electronic non-invasive medical instrument capable of measuring changes in heart rate (HR) and SpO_2 at the fingertip and its upgrade to the standards; HL7 and IEEE 11073-10404:2008, its design, and its validation against the three existing devices. Variables (SpO_2%, Ppm and Temperature) were compared, and its performance and impact were discussed the addition of the WiFi technology allows a better communication between devices, causing a greater impact in global competiveness.

Keywords: HL7, OBX message, Pulse Oximetry, Optical Sensor, Heart Rate level, WiFi protocol.

1. INTRODUCTION

Health is very important to be a competitive person in a world like ours, so this paper is related about a biodevice (Oximeter WiFi) for health. Pohjola, Venturini (2009) say that ICT investments have a positive impact on economic growth of GDP, also Edwards (2001) said that areas need large investments in ICT research, development, education, infrastructure and health to generate economic growth. Baily, Katz and West (2011) suggest that investment of ICT innovation as a key factor in the economy, so we can say that the oximeter is a technology that can help economic growth regardless of health satisfier. [2-3], [4], [5].

The pulse oximeter has become a vital NICU (neonatal intensive-care unit) instrument [15], [16] and may have been adopted as a standard [17]. Various studies have concluded that with better technology, pulse oximeters would provide highly accurate measurements of oxygenation [17-18]. Bierman demonstrated that with other factors being equal, pulse oximetry significantly reduced the need for arterial blood gas collection [17], [19-20]. Zengel examined the effects of subareolar isosulfan blue injection on pulse oximeter (SpO_2) readings and concluded that Time to peak SpO_2 fall, and the recovery period, are delayed in the subareolar technique [21].

On the another hand Rodriguez, Garrido, Martinez, & Garcia (2013) presented a paper related to the accuracy of pulse oximeters, including a brief introduction to the pulse oximetry operation principles, calibration procedure, and discussing the main aspects related to the accuracy of measurements and staying that the magnitudes of the errors due to variations of the wavelengths of the LEDs used were highlighted together with the risks that those errors produced to the patients [1].

Hülsbusch, et. al (2010) studied cardiovascular diseases of irregularities in the human cardiovascular system developing a miniaturize in-ear pulse oximeter, based on a micro-optic in-ear sensor. The resulting signal was then transferred wirelessly to a personal digital assistant (PDA) smart phone or PC where the heart beat, oxygen saturation (SpO_2), breathing frequency and slower perfusion rhythms could be calculated. This contribution introduced the system concept of the monitoring [13].

Besides, the oxygen is vital to the functioning of each cell in the human body. Without oxygen for a prolonged amount of time, cells will die. Thus, oxygen delivery to cells is an important indicator of a patient health. Several methods have been developed to analyze oxygen delivery. Pulse oximetry is a common, noninvasive method used in clinical environments [6].

Oxygen transportation is performed through the circulatory system. Deoxygenated blood enters the heart where it is pumped to the lungs to be oxygenated. In the oxygenation process, blood passes through the pulmonary alveoli where gas exchange (dif-fusion) occurs (See Figure 1). Carbon dioxide (CO_2) is released and the blood is oxygenated, afterwards the blood is pumped back to the aorta [7].

Blood red cells contain a protein called hemoglobin. Red cells with oxygenated hemoglobin circulate in the blood through the whole body, irrigating tissues. When blood gets in contact with a cell, the red cells hemoglobin releases oxygen and becomes Deoxyhemoglobin (Hb) (deoxygenated hemoglobin) [7].

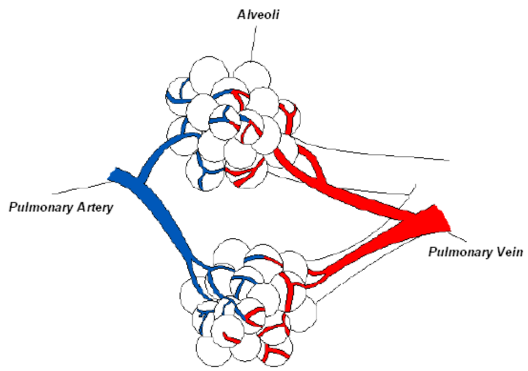

Fig. 1. Pulmonary alveoli.

More over pulse oximetry is the non-invasive measurement of the oxygen saturation (SpO_2). And pulse oximetry systems are based on two principles related to the characteristic of blood flow rate in the context of the oxy-hemoglobin and deoxy-hemoglobin status. Both oxy-hemoglobin and deoxy-hemoglobin are different in their absorption of red (660 nm to 750 nm) and infrared light (850nm-1000nm), and because the volume of the arterial blood in tissue changes as the pulse changes. With each heartbeat, the volume of the arteries becomes larger before the blood enters the capillaries. This change makes possible for the oximetry system to differentiate the arterial blood from all other absorbing substances [8], [9]. Figure 2 shows the absorption levels of oxygenated and deoxygenated blood at different wavelengths.

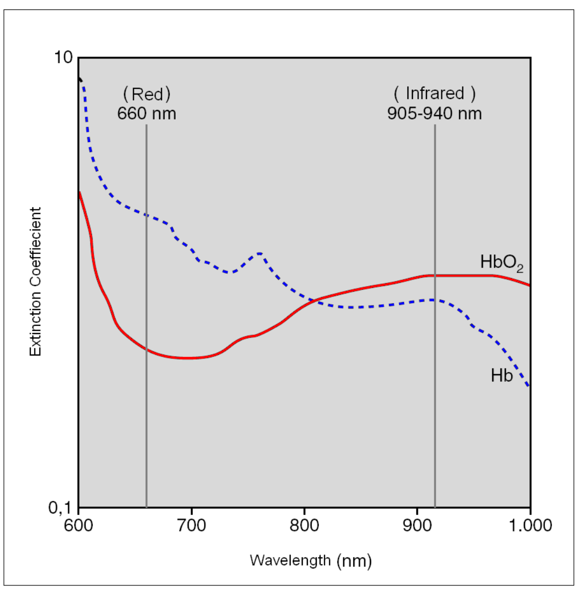

Fig. 2. The absorption levels of oxygenated and deoxygenated blood at different wavelengths.

When light is emitted into the body tissue, some light will be absorbed by the skin, bones and muscle tissue. This represents the static direct current (DC) component of the signal received at the photo detector receiver. The pulsatile flow in arteries and arterioles during diastole and systole will create some variation in light intensity. This will produce the alternating current (AC) part of the signal [9]. At this point the absorption that occurs is known as the Beer-Lambert Law. Both AC and DC components are shown in Figure 3. [10].

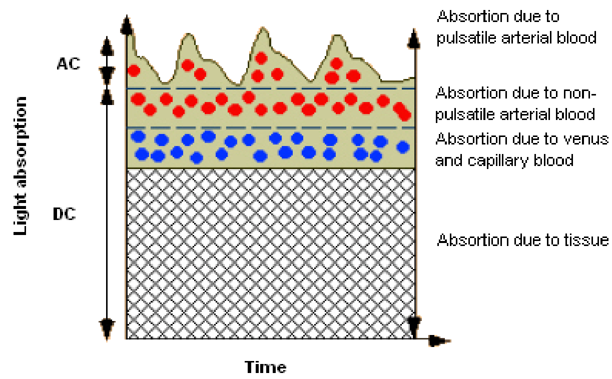

Fig. 3. Light absorption through living tissue.

As mentioned above, we agree with Shafique, Kyriacou, & Pal (2012), who investigated Photoplethysmography (PPG), which is a technique widely used to monitor volumetric blood changes induced by cardiac pulsations and pulse oximetry uses the technique of PPG to estimate arterial oxygen saturation values (SpO_2). In poorly perfused tissues, SpO_2 readings may be compromised due to the poor quality of the PPG signals. A multimode finger PPG probe that operates simultaneously in reflectance, transmittance and a combined mode called "transreflectance" was developed, in an effort to improve the quality of the PPG signals in states of hypoperfusion. Experiments on 20 volunteers were conducted to evaluate the performance of the multimode PPG sensor and compare the results with a commercial transmittance pulse oximeter. A brachial blood pressure cuff was used to induce artificial hypoperfusion. Results showed that the amplitude of the transreflectance AC PPG signals were significantly different ($p < 0.05$) than the AC PPG signals obtained from the other two conventional PPG sensors (reflectance and transmittance). At induced brachial pressures between 90 and 135 mmHg, the reflectance finger pulse oximeter failed 25 times (failure rate 42.2%) to estimate SpO_2 values, whereas the transmittance pulse oximeter failed 8 times (failure rate 15.5%). The transreflectance pulse oximeter failed only 3 times (failure rate 6.8%) and the commercial pulse oximeter failed 17 times (failure rate 29.4%) [29].

2. DESCRIPTIVE AND METHODOLOGICAL SECTION

This research was supported by an experiment, at the "Hospital de Ortopedia y Traumatologia - Dr. Victorio de la Fuente Narvaez" in Mexico City, in 2013, with a sample of 32 patients. The experiment consisted of taking samples of variables 1) SpO_2%, 2) Ppm and 3) The temperature, which are shown in Figure 8 and are described in Table 1. The measurements were taken by three different devices: Nonin, Mazimo, and WiFi oximeter.

Table 1. Study variables

Variable	Description
SpO_2%	Oxygen level (0 to 100%)
Ppm	Pulses per minute (0 to 200ppm)
Temperature	Body Temperature (0 to 100ºC)

An intensive care monitor alarm has been a major burden on both nurses and patients. Between 44% and 63 % of alarms are caused by pulse oximeters, with 94 % of these being non-significant [22-24]. Any technique for measuring pulse oximeter saturation (SpO_2) has been developed using a mathematical manipulation of the pulse oximeter red light and infrared light absorbance to identify and subtract the noise components associated with these signals [25]. Theoretically the pulse oximeter analyzes the light absorption of two wavelengths from the pulsatile-added volume of oxygenated arterial blood ($AC_{red\ light}/DC_{infrared\ light}$) and calculates the absorption ratio "R" using the following Eq. 1.

$$R = \frac{AC_{660}/DC_{660}}{AC_{940}/DC_{940}} \qquad (1)$$

SpO_2 is taken out from a table stored on the memory calculated with empirical formulas. A ratio of 1 represents a SpO_2 of 85%, a ratio of 0.4 represents SpO_2 of 100 %, and a ratio of 3.4 represents SpO_2 of 0 %. For more reliability, the table must be based on experimental measurements of healthy patients.

Another way to calculate SpO_2 is taking the AC component only of the signal and determines its ratio by using Eq. 2. SpO_2 is the value of "R" X 100.

$$R = \frac{Log_{10}/(I_{AC_{660}})}{Log_{10}/(I_{AC_{940}})} X100 \qquad (2)$$

Where:

I_{ac} = Light intensity at 1 (660 nm) or 2 (940 nm), where only the AC level is present.

R= Absorption ratio of light.

The system consist of five parts; sensor, amplifier, processing, LCD display and WiFi communication protocol, as shown in Figure 2.

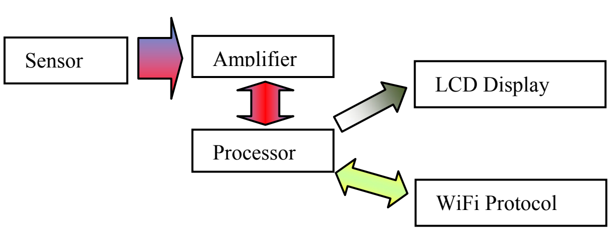

Fig. 4. Block diagram showing the flow of operation for the Pulse Oxymetry WiFi System.

Sensor of Pulse Oximetry

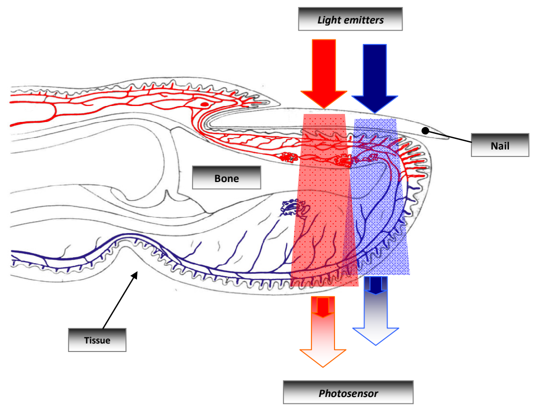

Fig. 5. Sensor orientation for light transmittance in the designed pulse oximeter.

The WiFi Pulse Oximeter system have a probe (sensor), is composed by two LEDs, and a photo-detector. The two LEDs used in the sensor part are the red and infrared (See Figure 5), and the signal collected by from the photo-detector. To perform our tests, we used the finger. The detectors must be highly sensitive and be able to measure the weak emission through to the tissues. It requires a sample and hold circuit (sampling and maintenance) for reconstructing waveforms in each of the lengths. Likewise, timing circuits which control the driving circuits of both LEDs can be used in the section of sample and hold circuits. The output of these circuits are then taken to a bandpass filter section designed to operate at frequencies of 0.5 Hz to 5 Hz Intended primarily to eliminate DC component and high frequency noise (See Figure 6) [12].

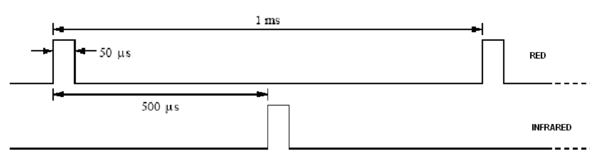

Fig. 6. Timing output signal to the sensor.

Acquiring the signal

The optical receiver element is a photodiode. The acquisition of the signal is obtained by amplifying and filtering the output of the phodetector. The amplified photocurrent is a moderate-voltage, low-impedance output, which is then taken to a bandpass filter section designed to operate at frequencies of 0.15 Hz to 7.5 Hz. This is mainly intended to eliminate the DC component and high frequency noise, as seen in Figure 7. [12]

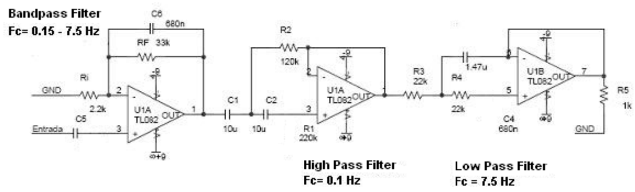

Fig. 7. Filtering and Amplifying Circuits.

Processing Pulse Oximetry Signal

The acquired is supplied to a Programmable Interface Controller (PIC) which will be converted it from analogue into digital signal through the built-in 12bit Analogue to Digital Converter. However, this conversion requires a C programming software and C18 compilation process to generate the Hexadecimal ".hex" file. An example of line code in C18 to calculate de SPO_2%, applying (2) is given in Eq. 3

```
Calculated_Spo2 = (((log((1 / red)) / (log((1 / infrared))))*100);         (3)
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Display of Pulse Oximetry

For the device to be user friendly the measured values are shown; the output produced by the PO will be displayed via a Liquid Crystal Display (LCD) screen. The organization characters are as shown in Figure 8.

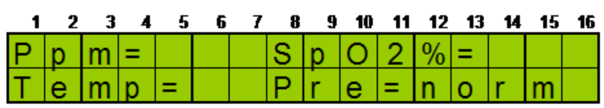

Fig. 8. Display test data processed as the Table 1.

The WiFi protocol and communication

The implementation of the WiFi protocol uses the Microchip TCP/IP Stack, a suite of programs that provides services to standard TCP/IP-based applications (HTTP Server, Mail Client, etc.). The software stack has an integrated driver that implements the API that is used in the modules for command, control, management and data packet traffic [11].

Once the layer "StackTask" is on line, this is used to communicate and transmit the final acquired signal SPO_2% between the Microchip TCP/IP Stack and TCP protocol, see Figure 9.

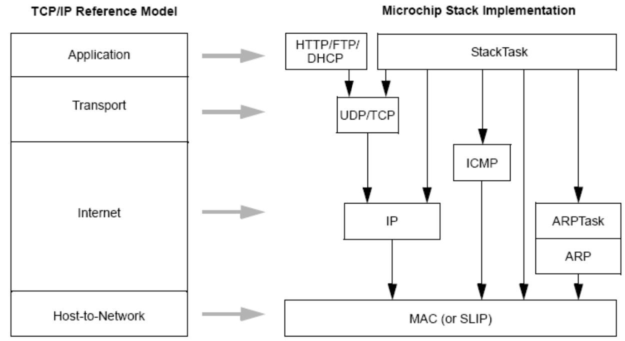

Fig. 9. Comparison between: Microchip TCP/IP Stack Structure and TCP/IP Reference Model.

Some connectivity issues were solved using a TCP/IP prototype interface, where we used the Microchip TCP/IP Stack as part of the oximeter hardware as shown in Figure 10.

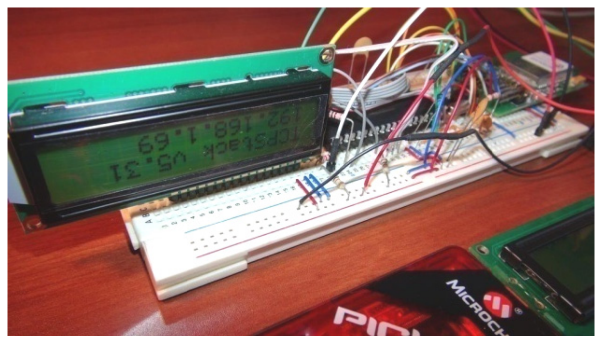

Fig. 10. Prototype: WiFi communication.

When the device has the final results (SpO_2% and the HR), we use a micro embedded WiFi card to communicate the microcontroller with the most nearest access point (AP) to enable the WiFi Pulse Oximeter system to be reachable for other devices like laptops, computers, Smartphone's connected to the same AP, as shown in figure 11. The area where the oximeters operated, it is called wireless body area network (WBAN).

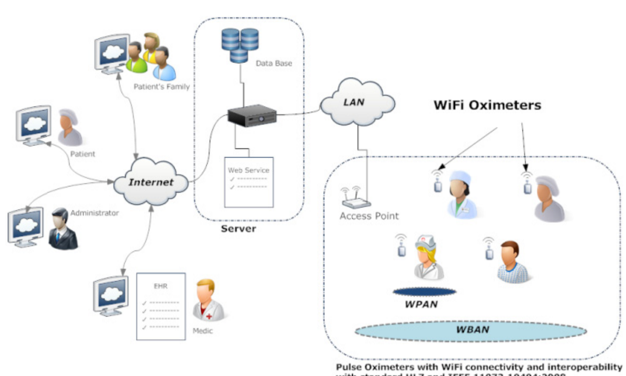

Fig. 11. Oximeters with WiFi connectivity over the network.

The standards; HL7 and IEEE 11073-10404:2008

It is essential for systems such as health devices, to interoperate among each other to have a common communication standard. The ISO/IEEE 11073 family of standards for medical devices has existed for many years and was originally developed for hospital based equipment and specifically for the intensive care environment. The original protocol, based on the full OSI 7 layer model, was often criticized as being heavyweight and complex. In its current form, it was not considered appropriate as the basis of a new standard for personal health data (PHD) devices (See Figure 12). [27]

In order to solve interoperability among PHDs, a non-profit organization involved in the development of international health care informatics interoperability standards, brought out the Health Level Seven (HL7) standard (e.g., HL7 v2.x, v3.0, HL7 RIM).

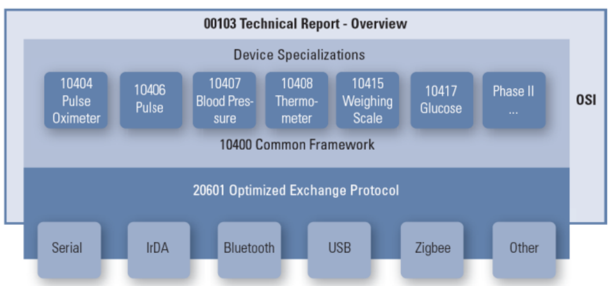

Fig. 12. Overview: IEEE PHD 11073 Framework.

Once the results were ready to be transmitted, the standard IEEE 11073-10404 [28] was used to create a data frame, which contains the variables: idDevice, date and time, idMeasure, deviceSerialNumber, wifiMacAdrees, batteryState, temperature, spo2, ppm, etc. All those data were packaged into an OBX (Observation Segment) message, which is a segment used to transmit a single observation or observation fragment. It represents the smallest indivisible unit of a report. It is used to communicate through all the platforms, which uses the Health Level Seven (HL7).

OBX message

The principal mission of an OBX is to carry information about observations and results in HL7 standard report messages. It represents the smallest indivisible unit of a report [30].

The WiFi Oximeter generates an OBX message, which function is to encapsulate the previous measures in a single message; it is going to be transmitted using the Microchip TCP/IP through the Internet.

Here is an example of an OBX message and its detail description, every single field has an important meaning (See Figure 13). This segment its part of multiple message types that transmit patient clinical information. Essentially, the OBX segment is used to transmit patient clinical information in a variety of formats. [30].

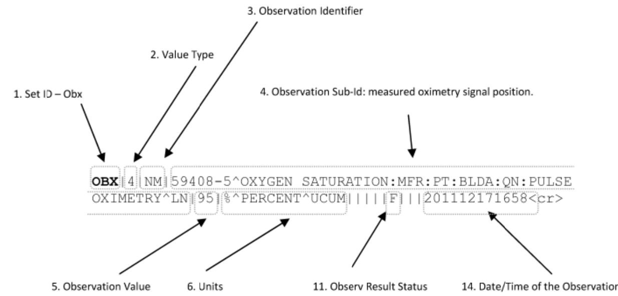

Fig. 13. OBX message.

The final version of the Pulse Oximeter with WiFi connectivity and interoperability with standard HL7 and IEEE 11073-10404:2008 is built with many scientific and technology components such as the optical theory and biometric analysis through a biosensor, also the acquisition and filtering signal are crucial to determine temperature, heart rate and more. The algorithms are important to calculate the SpO2%. Although, enable WiFi communication, it was required more efforts to be operational than we expected. Now this prototype allows us to communicate in real time with other platforms which uses the IEEE PHD 11073 Framework and the HL7. The full hardware is shown in Figure 14, where the main components are visible.

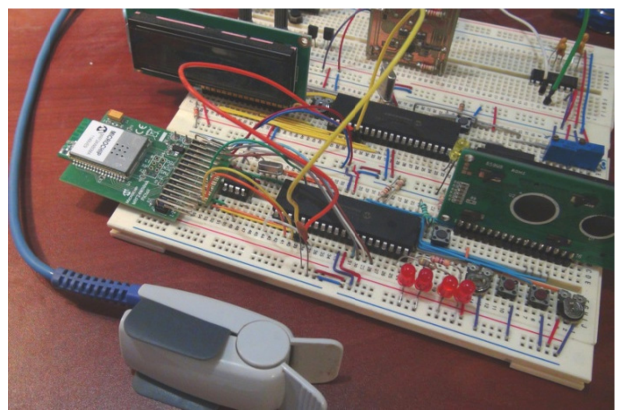

Fig. 14. Oximeter with WiFi connectivity and interoperability with standard HL7 and IEEE 11073-10404:2008.

3. IMPLEMENTATION

Following [26], measurements were taken by three devices (Nonin, Mazimo and WiFi Oximeter), SpO_2% values below 95% where, then by a second measurement, and only the highest value was recorded.

The first implementation was made at the “Hospital de Ortopedia y Traumatologia - Dr. Victorio De La Fuente Narvaez” in Mexico City, with optimum results at the moment of testing the WiFi Oximeter [8]. All tests were reviewed by specialist doctors under the ISO 9919:2005, in which ISO defines the procedure to prove the Oximeters. [14] Figure 15 shows the tests.

Fig. 15. Oximeters test; Mazimo, Nonin and Oximeter WiFi in a patient.

4. RESULTS AND DISCUSSION

The results obtained from the three devices Nonin, Mazimo and Oximeter WiFi, are quite similar as shown in Table 2. Regarding the temperature, only the WiFi Oximeter device, Table 2 shows the values.

Table 2. Results from the Three Treatments

	Nonin		Mazimo		Oximeter WiFi		
	SpO_2%	PPM	SpO_2%	PPM	SpO_2%	PPM	Temperature
Min.	87.00	70.00	86.00	69.00	86.00	70.00	29.00
Max.	99.00	94.00	100.00	93.00	100.00	94.00	32.00
Average	94.16	82.84	93.72	82.78	93.78	83.00	30.38

Figure 16 shows visually the values obtained for the SpO_2% variable, which gives reliability on the results by using the proposed WiFi device.

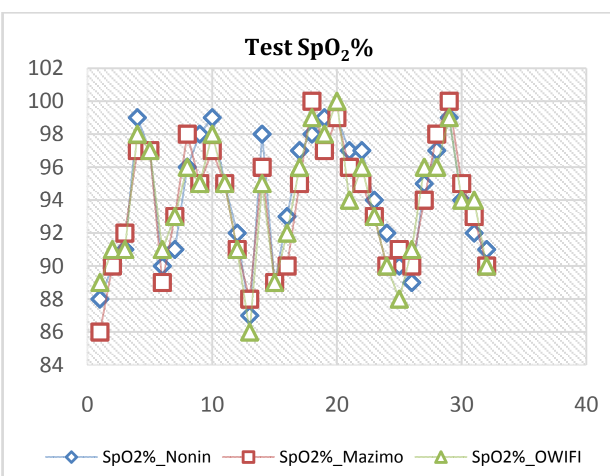

Fig. 16. Test Results SpO_2%.

Figure 17 shows the values obtained for the pulse per minute variable, which gives reliability on the results by using the proposed WiFi device.

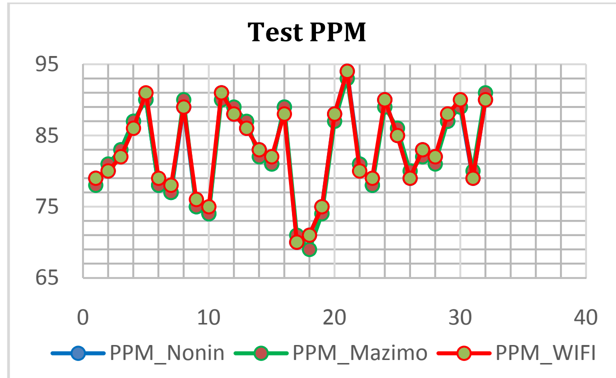

Fig. 17. Test Results PPM.

Finally, figure 18 shows visually another values obtained for the temperature variable, which is a variable does not included in the others oximeter and it is useful for medical purposes. This is the analysis of the results. Figures 16 and 17 show a similar behaviour and that was the aim of this WiFi Oximeter.

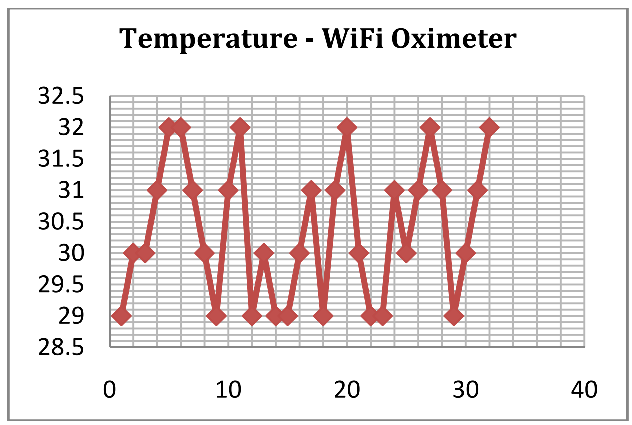

Fig. 18. Test Results Temperature.

Discussion: Many authors have stated the need of interoperability aiming to obtain fast and reliable measurements. Additionally, as observe in Figure 16 and 17, though the similarity of the measurements the WiFi Oximeter device gives the temperature, which can be consider as an added value. This would promote an economic growth of the Health Care Industry by having low-cost, high-reliable measurement devices obtaining more variables, as pointed out by Pohjola [4] and Venturini [5].

5. CONCLUSIONS AT THE MOMENT

The preliminary conclusions are: **First**, from the electronic point of view: the needed research and tests were carried out to join the project and brought it to a first phase, its construction. **Secondly**, notwithstanding that results were successful in its implementation, doctors made it clear that further testing in a more specialized area is needed, and of course, this is a more advanced version of this oximeter. Because doctors **asked if the oximeter could autosave the results into a system or database and the answer was yes**, this question gave us the opportunity to develop as a second phase of the oximeter. The features are emphasized: scalable technology, on-line monitoring, provides connectivity and networking, will provide more timely and easy monitoring, use of Standard ISO 9919:2005, standard HL7 and IEEE 11073-10404:2008 and others. This design is protected in Mexico by the Patent, Number: **MX/u/2009/000216.**

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