DEVELOPMENT OF A PULSE OXIMETER AND BLOOD PRESSURE MEASUREMENT DEVICE

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Abstract: The aim of this study was to develop a device that measures both oxygen saturation (S_pO_2) and Blood Pressure (BP), non-invasively, continuously and without a cuff. The pulse oximeter was developed for transmission and reflection mode, for use in finger and wrist, respectively. The oxygen saturation results obtained with the developed device placed on the wrist reveled an high relation with an market device. For BP measurement there were tested 3 different combination of sensors localizations to obtain Pulse Transit Time (PTT): ECG and pulse oximeter on the finger, ECG and pulse oximeter on the wrist and pulse oximeter on the wrist and photoplethismogram on finger, and two calibration modes: for each subject - without input parameters - and general - with one input parameter (height). The results reveled better correlation between the BP estimated with the first calibration and the reference method (cuff-based) than for the second calibration.

1 INTRODUCTION

The health condition of patient can be evaluated according to different parameters, including: heart rate (HR), Blood Pressure (BP), respiratory rate, temperature and Oxygen Saturation (S_pO_2) (Haahr, 2006).

According to World Health Organization (WHO), cardiovascular diseases are the main cause of deaths (Wong et al., 2009) (WHO, 2011). In Portugal, cardiovascular diseases are the leading cause of death, accounted for about 40% of deaths in 2009 (PS, 2011).

Thus, there is an increasingly demand for non-invasive and continuous monitoring of important factors for assessing and preventing these and other diseases.

The oxygen saturation (S_pO_2) is an efficiency indicator of gas exchange in the lungs and is quite important to determine deficiencies in respiratory system, diagnosis of diseases (such as cyanosis or hypoxemia), or anesthesia prescription (Daminani, 2010).

This parameter can be extracted from a Pulse oximeter. Pulse oximetry is an optical and non-invasive technique tha allows to access the percentage of oxygen in blood (Sola et al., 2005). This technique measures the blood oxygen saturation during cardiac cycle by shinning an infrared (IR) and red ligth-emission diode (LED) through the tissues. From the different tissues ligth absorption results a direct current (DC) and alterning current (AC) (Reisner et al., 2008).

The estimation of S_pO_2 is made switching the red and infrared LEDs in a higher frequency than cardiac frequency. Thus, S_pO_2 is obtained by applying Equation 1:

$$S_pO_2 = A - B * R, with \quad (1)$$

$$R = (AC_{red} * DC_{IR})/(AC_{IR}/DC_{red}) \quad (2)$$

A and B are constants extracted from a calibration curve. AC_{red} and DC_{red} represent the magnitudes of the pulsatile and DC parts of the red-PPG, respectively. $AC_{infrared}$ and $DC_{infrared}$ represent those magnitudes but from IR-PPG (Reddy et al., 2009).

S_pO_2 can be measured in two modes: transmission and reflection. In the first the probe is placed so that the LED and the photodetector stay on opposite sides of the tissue and is measured the light that is transmitted. In the second this two components are placed in the same side of the tissue and is measured the light that is reflected by the deeper structures (like bone) and returns to the surface (Reisner et al., 2008).

The combination of pulse oximeter with an ECG signal, allows to obtain another important parameter for patient clinical state evaluation, the Pulse Transit

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Time (PTT) that correlates with the BP. PTT refers to the time it takes a pulse wave to travel between two arterial sites (Naschitz et al., 2004).

One of the factors that have great influence on BP is the speed at which a blood pulse moves (velocity pulse propagation - VPP). This is proportional to BP. So, PTT and BP are inversly proportional (Naschitz et al., 2004).

The measurement of this parameter implies the detection of an arterial pulse arrival at two different arterial sites. In typical measurement, this process depends on the acquisition of two different physiological signals: ECG and PPG. The first detects the ventricular depolarization by R wave. The second detects when the pulse wave arrives to an arterial extremity. However, measuring PTT can also be performed using two PPGs (Payne et al., 2006).

Although there are several approaches to how the BP and PTT are mathematically related, the relationship between BP and the PTT is described as *near-linear* (Payne et al., 2006).

The non-invasive method most used in clinical practice to perform non-invasive measurement of BP is the sphygmomanometer (cuff-based method). Although this gives results with good accuracy, the technique has the disadvantage of not detecting short-term changes, as so, not performing continuous monitoring of BP. Furthermore, the use of the cuff can lead to disorders that takes to patient's blood pressure changes due to the cuff inflation (Gesche et al., 2011).

The main goal of the present work was to develop a finger and wrist oximeter and to study a new technique to measure and continuously monitoring BP, using the ECG and PPG signals.

2 METHODS

Two different studies were made in order to obtain Oximetry and Blood Pressure. The first includes the development of a pulse oximeter (called oxiPlux), calibrated using a data of a market oximeter (*Nonin Onyx II, Model 9550*). The second study refers to the analysis of the best method to obtain BP from PTT measurements by comparing with a cuff-based method (sphygmomanometer: *Elta - Model: BM101 (HL168B)*).

All the sensors used were connected to bioPLUX Research, with acquisition frequency of 1 kHz, which sends data via bluetooth and in real-time to PC. The algorithms used to obtain the desired parameters were implemented offline in *Python*.

2.1 Pulse Oximeter

2.1.1 Sensor Description

It was developed a pulse oximeter with an automatic gain control (AGC). The sensor has a feedback mechanism, the DC loop, that consists of a photodetector, a transimpedance amplifier, two sample-and-holds (S/H), two low pass filters, two AGC circuits and two led drive current circuits. In the Figure 1 is shown the block diagram of the developed sensor.

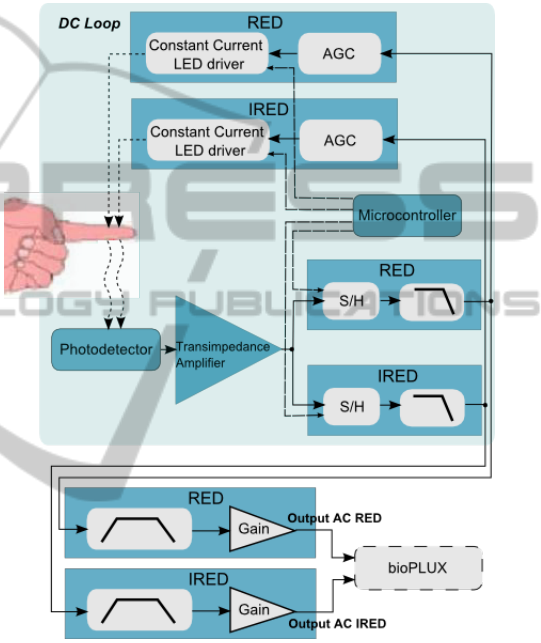

Figure 1: Block Diagram of the developed pulse oximeter.

After transimpedance amplifier, are the two sample-and-hold circuits that are used for demultiplexing the red and infrared signals. The sampling frequency and the LEDs turn on/turn off are set by a microcontroller. Both LEDs are never connected at same time.

The AGC circuits, implemented after the low pass filters, are composed of error amplifiers that enable to compare the received voltage in a reference channel with the output and adjusts the output voltage accordingly. That means that DC voltage of red and infrared circuits become equal to a reference voltage. Since this part of the circuit is connected to the led current driver part (a voltage to current convert that controls the LED current), the intensity of both LEDs can be controlled based on the light that is received by the photodetector.

After the DC loop there is a 0.4Hz high pass filter, followed by a Gain Stage and another Low Pass Filter

(cutoff frequency 7Hz).

The output of the sensor is two AC signals: one from red and another from infrared absorption. Having a DC stabilized tension (for both wavelengths), the Equation 2 simplifies to:

$$R' = AC_{red}/AC_{infrared} \quad (3)$$

The AC signals were processed in order to obtain R' and, after calibration, S_pO_2. The developed algorithm can be divided in four steps:

- Detection of red and infrared PPG peaks positions;
- Application of Equation (3) in the peaks positions detected above, to obtain R';
- Average of five consecutive values of R';
- Application of calibration equation to obtain S_pO_2.

2.1.2 Data Aquisition and Calibration

It was studied the developed pulse oximeter working in relfection mode, placed on the wrist, over the ulnar arterie area, in normoxia conditions. A group of 6 volunteers, ages 22-27 participated in that study. The individuals were considered healthy, without any known disease. All the measurements were made in rest.

The pulse oximeter calibration was made by comparison. The data (R) obtained with the developed device was fit to the data (S_pO_2) obtained with Nonin, using a linear regression.

2.2 Blood Pressure by Pulse Transit Time

Table 1 and Figure 2 shows the PPTs obtained from different sensor combinations for the BP study.

Table 1: Different sensors combinations used to obtain PTT - Pulse Transit Time.

Sensors	PTT
ECG oxiPlux in finger	PTT1
ECG oxiPlux in wrist	PTT2
oxiPlux in wrist oxiPlux in finger	PTT3

In order to obtain BP from PTT, a group of acquisitions were made, with a 3-lead ECG sensor (ecgPLUX) placed at cheast (V2 derivation), oxiPLUX on rigth index finger, oxiPlux on rigth wrist and sphygmomanometer in left wrist. A group of 6 individuals, ages 22-27 , heigth 1.55 m - 1.96 m, without any known disease, were volunteers. All the measurements were made at rest.

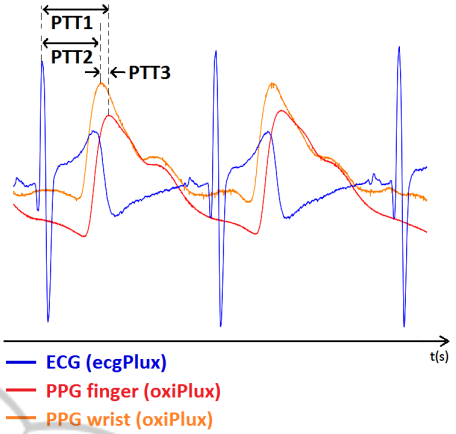

Figure 2: Typical PPG and ECG output signals and PTTs obtained by the developed algorithms.

The acquisitions were made during 10 minutes and the sphygmomanometer was connected every two minutes (aproximately), in order to obtain BP, systolic (SBP) and diastolic (DBP).

2.2.1 ECG and PPG

From ECG and PPG signals, the PTT (PTT1, PTT2) was calculated as the difference between the R wave of ECG and the maximum point of red PPGs. The algorithm used for that calculation can be resumed in 3 points:

- Detection of ECG R peak positions;
- Detection of red PPG peak positions;
- Obtain the difference between the position of ECG peak and PPG peak - PTT;

With the PTT values, the BP was estimated by fitting the data obtained from the cuff-based method values and the PTT, applying a linear regression. That estimation was made using two different aproaches:

- Calibration 1 - for each subject and without input parameters (Cal 1 - individual curve calibration for each user), as shown in Equation (4);
- Calibration 2 - general and with one input parameter (Cal 2 - same calibration curve for all users), as shown in Equation (5).

$$BP = m * PTT + b \quad (4)$$

$$BP = m * (PTT/f) + b \quad (5)$$

The variables m and b are the fitting values and f is a body correlation factor related to height (Fung et al., 2004).

2.2.2 PPG and PPG

By using only PPG signals (on the finger and on the wrist), the developed study aims to obtain PTT (PTT3) and estimate the BP. The resumed algorithm used to obtain that parameters is:

- Detection of finger PPG peak positions;
- Detection of wrist PPG peak positions;
- Obtain difference between the positions obtained above - PTT;

With PTT values BP was estimated in two, applying Calibration 1 (Equation 4) and Calibration 2 (Equation 5).

3 RESULTS

3.1 Oximetry Study

The main objective of that study part was to obtain an instrument that gives quantitative measurements S_pO_2. Calibration was a crucial part of the whole process and so this was the first step of the study. It was obtained a calibration curve for this sensor, working in reflection and for wrist placemnet, witch have a R^2 iqual to 0.74.

The Table 2 presents presents a comparison between the S_pO_2 (%) results obtained with the oxiPlux probe placed at wrist and Nonin. The mean and the standard deviation (σ) of S_pO_2 for both sensors were calculated.

Table 2: S_pO_2 (%) obtained with oxiPlux with wrist probe and Nonin: comparison results in normoxia.

Subject	oxiPlux wrist: $S_pO_2 \pm \sigma$	Nonin: $S_pO_2 \pm \sigma$
1	97.41 ± 0.14	97.29 ± 0.76
2	96.87 ± 0.16	96.38 ± 0.52
3	96.19 ± 0.16	96.13 ± 0.64
4	96.97 ± 0.29	97.13 ± 0.64
5	98.17 ± 0.41	97.31 ± 0.21
6	98.33 ± 0.52	98.54 ± 0.36

The results obtained from the oxiPlux placed on the wrist (Table 2) are in the range of values obtained from Nonin. The Nonin accuracy is $\pm 2\%$ (Nonin, 2011), so for 97% oxygen saturation it is possible that the real oxygen saturation value is $97\% \pm 1.94$. Calculating that error for all the subjects is possible to verify that the S_pO_2 obtained from oxiPlux is allways in that range of values obtained from Nonin.

The oxiPlux sensor uses a continuous acquisition system. It allows to detect all the changes in S_pO_2 values (which occur at intervals of 1 ms). The results obtained from Nonin were collected at intervals of 10 s, so the S_pO_2 variations that may have occurred between that interval were not detected. This may explain the small discrepancies in the results.

Despite the small differences between oxiPlux and Nonin, the outcomes show that oxiPlux can detect changes in S_pO_2 when a reflection mode is used, with the probe placed on wrist.

3.2 Blood Pressure Study

In the BP study, the calibration results obtained are more accurate for SBP than for DBP. The coeficiente of determination interval values for Calibration 1 are presented in Table 3, for SBP and DBP.

Table 3: Coeficient of determination (R^2) interval values for estimation of SBP and DBP from different PTTs - Calibration 1.

PTT	SBP:	DBP:
PTT1	0.14 - 0.95	0.10 - 0.79
PTT2	0.73 - 0.90	0.18 - 0.41
PTT3	0.40 - 0.99	0.22 - 0.99

For Calibration 2 the obtained R^2 results for SBP estimation (obtained from PTT1 and PTT2) are represented in Figure 3.

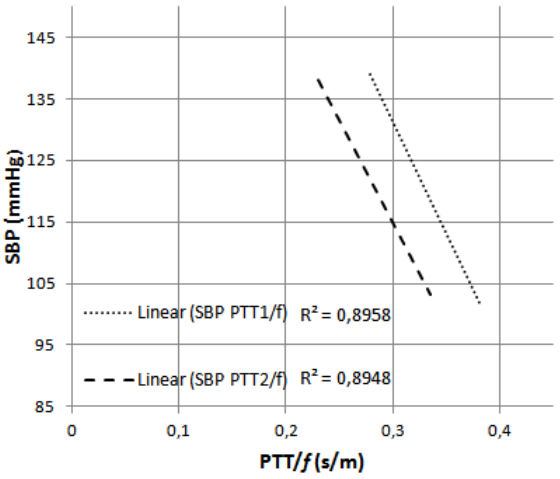

Figure 3: Calibration curves obtained from Calibration 2 for SBP.

Table 4: Comparison between SBP (mmHg) estimated with Cal 1 and Cal 2 and the cuff values.

Subject	Cuff	SBP from PTT1: Cal 1: SBP $\pm\sigma$ Cal 2: SBP $\pm\sigma$	SBP from PTT2: Cal 1: SBP $\pm\sigma$ Cal 2: SBP $\pm\sigma$	SBP from PTT3: Cal 1: SBP $\pm\sigma$
1	130.86 ± 6.33	135.91 ± 3.33 133.13 ± 1.90	136.12 ± 4.10 137.39 ± 3.14	138.81 ± 17.03
2	116.67 ± 3.88	109.75 ± 11.18 135.50 ± 3.94	114.81 ± 0.83 148.39 ± 2.58	121.09 ± 3.02
3	132.00 ± 7.18	131.47 ± 11.13 136.93 ± 1.56	138.97 ± 12.93 137.93 ± 1.88	141.42 ± 11.53
4	131.8 ± 6.61	123.87 ± 6.39 121.53 ± 5.07	132.57 ± 1.98 127.29 ± 3.22	139.55 ± 6.41
5	120.33 ± 2.16	119.21 ± 1.17 118.70 ± 2.74	120.31 ± 1.94 120.43 ± 3.53	120.62 ± 2.37
6	104.83 ± 2.71	104.20 ± 2.86 108.11 ± 17.88	103.82 ± 2.63 107.62 ± 22.58	102.25 ± 4.50

Table 5: Comparison between DBP (mmHg) estimated with Cal 1 and Cal 2 and the cuff values.

Subject	Cuff	DBP from PTT1: Cal 1: DBP $\pm\sigma$ Cal 2: DBP $\pm\sigma$	DBP from PTT2: Cal 1: DBP $\pm\sigma$ Cal 2: DBP $\pm\sigma$	DBP from PTT3: Cal 1: DBP $\pm\sigma$
1	68.00 ± 4.76	69.53 ± 1.39 70.67 ± 0.31	69.53 ± 1.57 71.70 ± 0.53	67.61 ± 7.68
2	70.83 ± 2.99	74.05 ± 1.71 71.07 ± 0.66	71.01 ± 0.92 73.57 ± 0.43	77.24 ± 2.71
3	69.00 ± 5.06	69.25 ± 5.63 71.30 ± 0.26	67.75 ± 0.92 71.79 ± 0.32	74.58 ± 3.87
4	72.67 ± 4.97	70.33 ± 3.73 68.74 ± 0.84	77.83 ± 5.04 69.99 ± 0.54	72.88 ± 4.72
5	68.60 ± 1.95	68.30 ± 1.70 68.27 ± 0.45	68.20 ± 1.29 69.17 ± 2.62	67.05 ± 2.08
6	61.60 ± 1.14	61.77 ± 1.08 66.51 ± 2.98	61.75 ± 0.61 66.65 ± 3.83	62.16 ± 0.97

After obtaining the calibration curves (Calibration 1 and Calibration 2), the developed algorithm was applied and the results obtained for SBP and DBP and the comparison with the cuff results are exposed in Table 4 and Table 5, respectively.

Concerning PPT3, the results for Calibration 2 shows a low value of R^2 so this results were not considered. This can be explained by the difficulty in to find the best sensor placement on the wrist. This fact can influence the magnitude and the quality of the signal and, consequently, become hard to collect a good signal for detecting PPG peaks. As the sensors are so close, on finger and on wrist, the PTT values obtained are so low that the false or the lack detections in one of them can lead to wrong calculations of PTT values and so a low R^2 for the calibration.

From the outcomes of Figure 3 it can be ascertained that for PTT1 and PTT2, R^2 has a value higher than 85%, showing a great relationship between the position of the sensors and SBP.

Analising Tables 4 and 5 is possible to verify that the values obtained for SBP and DPB are in most cases significantly related with the results obtained from cuff method. It is also possible to observe that some of the estimated BP are not in total concordance with the cuff ones, but the difference between the reference method and the estimated values are never above the 32 mmHg, for SBP. It is known that if the cuff is too small or if the cuff is placed over clothing, the SBP can vary between 10 mmHg and 40 mmHg (WelchAllyn, 2011). Thus, given the worst value for the difference between the estimated and the reference SBP (32 mmHg), the presented method can give a better estimation than an sphygmomanometer misplaced because this value is in the range of 10 - 40 mmHg.

The difference obtained in most cases can be explained by the low R^2 of some calibration Curves, specialy for DBP in Calibration 2. Other possible explanation is the need for adjust the body correlation factor used, f. It was tested just one body correlation factor (related to height), but the test of other body correlation factors could be advantageous for future studies.

This BP study allowed us to conclude that the customized calibration (Calibration 1) provides better results than the general (Calibration 2) for the tests performed in this work. Still, it can be assumed that with both calibrations was possible to obtain the SBP and DBP.

4 CONCLUSIONS

The main goal of the present work was to develop a device that allows the measurement of both S_pO_2 and BP without using a cuff, in a non-invasive, confortable and continuous mode.

The results show that the device works using both ECG and pulse oximeter, or using only an optical technique with the placement of two sensors, one in finger and other in wrist (with two pulse oximeters). It was also concluded that for BP estimation, a calibration for each subject, as an inicial calibration of sensor for each user, gives more accurate results than the BP estimated from a general calibration, even with an input parameter.

This study proved to be a starting point for the development of this device, that after some improvements, specialy in signal processing, will conduct to a medical device.

5 FUTURE WORK

A more effective calibration of the pulse oximeter, with more subjects and with an induced hypoxic state, is an important improvement for the next step of the oxiPlux development. The transition from offline to real-time software is also a development that will be done for this sensor.

For the BP study, all the used approaches recourse to linear regessions to relate PTT with BP, but an alternative approach could be made using non-linear relations to relate that two parameters. The study and application of other body correlation factors, related to height, can be also usefull to obtain more accurate results.

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