

Fetal pulse oximeter for in situ monitoring during labour and birth

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RESEARCH ARTICLE

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Abstract

The oxygen saturation of arterial blood which is normally measured by pulse oximeters is highly important. This paper introduces a miniaturization development of a non-invasive, reflective pulse oximeter. The aim of the project is to dramatically reduce the dimensions of a current device developed earlier already on the market whose size is 41x23x12 mm (LxWxH).

A further purpose is to invent a pulse oximeter which can be used to constantly monitor the oxygen saturation of a fetus during its birth and the labour period. Although similar devices can be found on the market, our oximeter is smaller in size and there is no connection cable which can cause discomfort to the mother.

This objective has been achieved by changing the main components of the prototype. Also, the Bluetooth module has been changed to an energy saving RF communication device. The main controller is also improved by adding a nanoWatt series QFN packaged PIC microcontroller to reduce power consumption. All of the analog electronic parts have been integrated into an ASIC (Applications Specific Integrated Circuit) chip.

In addition to improvements in the hardware, new control software has been written. This reshuffling means that a new evaluation board has been made for testing and controlling the newly designed oximeter. It is also easy to use. In addition, a conventional PC can be used for data display and processing which highly reduces the cost.

Keywords

non-invasive · pulse oximeter · in situ monitoring

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1 Introduction

Blood is one of the most important information carriers of the human body. Every detailed diagnosis begins with a complete blood test. Almost all symptoms of different kind of diseases can be detected in it. For example, adverse nutritional levels (high cholesterol or blood-sugar, etc.), various inflammations, improper functioning of the heart, smoking, diverse signs of vascular diseases and malfunction of the lungs, etc.

By continuously monitoring the oxygen saturation of a fetus during labour and birth, the numbers of caesarean deliveries and congenital defects can be reduced. In extreme situations, lives can be also saved by early detection of anoxia.

The project has been motivated by miniaturizing and improving our 5th generation reflectance pulse oximeter to achieve a compact sized easy to use device.

1.1 Theoretical background of oximetry measurements

Since the 1940's, it has been well known that the oxygenation of the blood can be determined by photometric methods [5]. Fresh oxygen saturated blood (which is conveyed through the arteries) has higher extinction coefficient values in the infrared wavelength range. In spite of this, the anoxic blood (which travels through the veins) has a higher extinction coefficient value in the red wavelength range. This phenomenon stems from the significant difference between the red, infra-red light absorption spectrum of oxyhemoglobin (HbO₂) which carries the oxygen molecules, and deoxyhemoglobin (Hb) which has already released them [1] (Fig. 1). In addition to determine these characteristics, pulse oximetry takes the heartbeat into account which appears like a periodic pulsation in the diameter of the veins (Fig. 2). This pulsation is detected by modern pulse oximeters using two light sources with different wavelengths resulting in two distinct reflected waveforms (Fig. 3). After detecting the extremities of each waveform the R ratio can be calculated using Eq. (1).

$$R = \frac{\ln \frac{I_{\max}(\lambda 1)}{I_{\min}(\lambda 2)}}{\ln \frac{I_{\max}(\lambda 2)}{I_{\min}(\lambda 2)}} \quad (1)$$

From the value R by using the Lambert-Beer deduction (Fig. 4), the exact SpO₂ value can be derived.

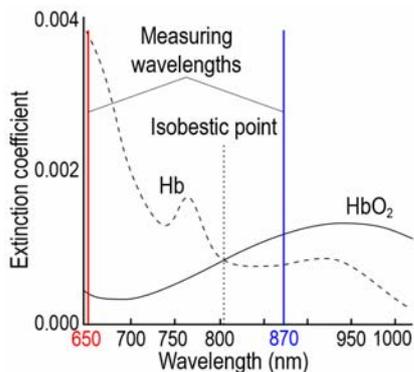


Fig. 1. Absorption spectrum of hemoglobin

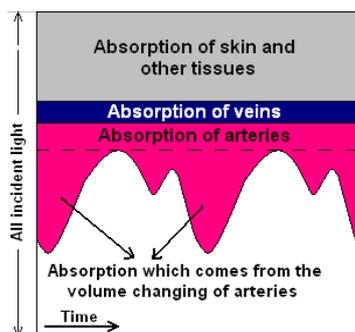


Fig. 2. The result of heartbeat as a periodic pulsation in absorption

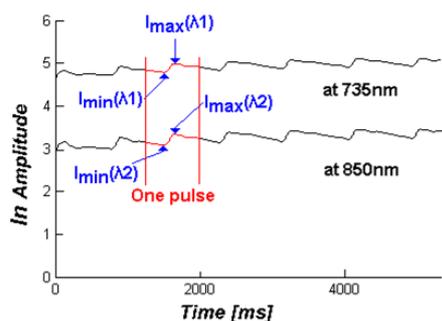


Fig. 3. Distinct waveforms measured at 735 nm and 850 nm

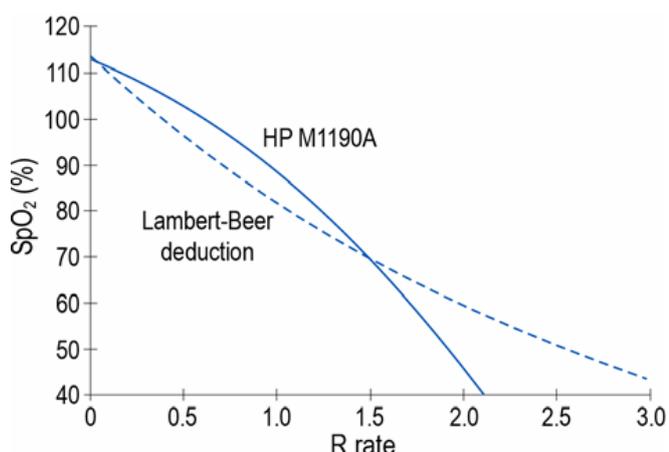


Fig. 4. Lambert-Beer deduction [6]

1.2 Fetus monitoring

Nowadays, the most commonly known fetus monitoring system is the cardiocograph, also known as an electronic fetal monitor or an external fetal monitor. It simultaneously mea-

sures both the fetal heart rate and uterine contractions using two separate disc-shaped transducers laid against the woman's abdomen. An ultrasound transducer measures the fetal heart-beat. A pressure-sensitive transducer, called a tocodynamometer (toco), measures the strength and frequency of the uterine contractions.

During internal monitoring, which is only possible once the waters have broken, a small sensor is attached by a thin catheter to the baby's scalp to directly and continuously monitor the fetal pulse oximetry and heart rate (Fig. 5). After positioning the sensor by use of a gold plated spiral shaped needle (Fig. 6), the catheter is removed.

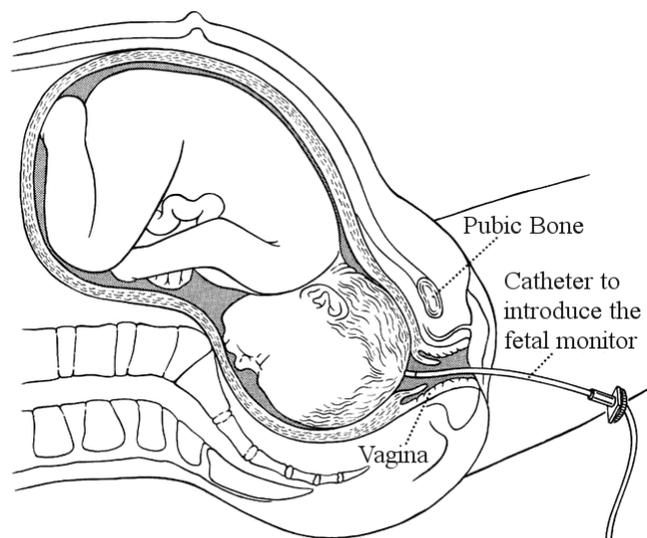


Fig. 5. Internal fetal monitoring [7]



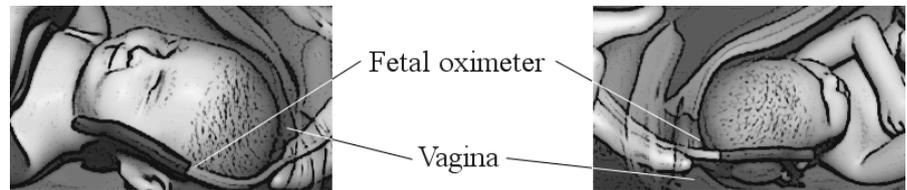
Fig. 6. Possible sensor head solution using a gold plated spiral shaped needle

For internal monitoring different equipment is used by Nellcor®. The oximeter device must be accurately aligned inside the mother's womb, laid against the fetus head and remain securely attached throughout the labour (Fig. 7).

The above mentioned components have a common attribute: each of them uses a wired communication device which limits the mother's freedom of movement during labour.

Currently there is a preference in the market for Nellcor®'s invasive measurements rather using than non invasive devices.

Fig. 7. Accurate position of Nellcor® oximeter [8]



2 Experimental analysis

The purpose of this project is to develop a miniaturized wireless, noninvasive pulse oximeter to make monitoring easier, more comfortable and able to greatly increase accuracy.

2.1 Brief introduction to an earlier type of pulse oximeter

The first step in the three years research and development resulted in an earlier generation of oximeter which can be seen in Fig. 8.

Main technical features without the claim of completeness:

- It has a dimension size of 41x23x12 mm (LxWxH)
- The measuring head is surrounded with black epoxy containing the two wavelength sources of light and the photodiode
- For programming and debugging purposes, the unit is equipped with an ICSP (In-Circuit Serial Programming [2]) connector
- The main controller programme (which was written in assembly programming language) runs on a PIC16LF876A [3] microcontroller
- For data converting and processing the microcontroller has a built in 10 bit A/D converter. This solution has a great advantage in that it reduces the number of components and therefore energy consumption
- The unit is powered by a 150mAh Li-ion battery
- For communication purposes a Bluetooth module is used

One of its biggest advantages is that any kind of USB Bluetooth module can be used for communication with the device. A simple software programme has also been written to display the results of measurements both in graphical and numerical formats. This application requires MATLAB for proper operation.

2.2 The newly developed oximeter

The newly developed oximeter has more important benefits than in earlier designs:

- Wireless communication is used which is convenient not only for the mother but for the fetus and the obstetrician.
- A conventional PC can be used to display results
- Ease of use
- Smaller in size

(Even though it has smaller physical dimensions it still needs a further reduction in size).

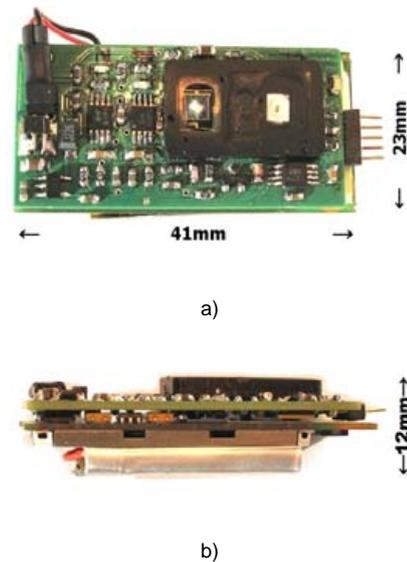


Fig. 8. a) top and b) side view of the previous oximeter

2.3 Size reduction

Additional miniaturization needs a change of components and their subsequent integration which can not be done without an Application Specific Integrated Circuit, the so called ASIC chip. This means that a redesigned architecture and a newly developed evaluation board has to be built.

2.3.1 New architecture, components and evaluation board

According to the hardware modification, the 6th generation oximeter has a different operating structure as shown in Fig. 9.

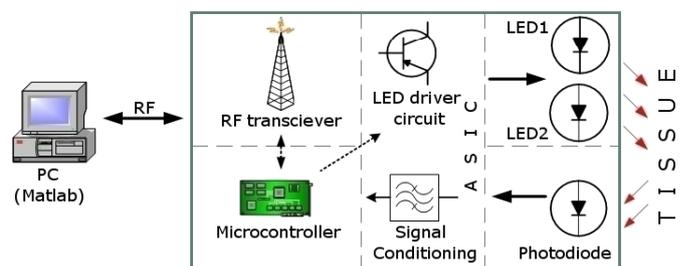


Fig. 9. Block diagram of the 6th generation device

In this case, the central unit role is fulfilled by the ASIC which controls the two LEDs. Signals from the photodiode are processed by the microcontroller after they are amplified and then conditioned also by the chip.

Thanks to the ASIC (2x2 mm surface and 480 μ m height) and the QFN packaged PIC18LF2420 [4] microcontroller, all the components can be placed on a PCB with a size no greater

than a €2 coin.

Because of the smaller dimensions of both the main controller chips and the auxiliary SMD components (mostly in size 0603), a new evaluation board is necessary. As a result, the new architecture can now be tested and the former control software implemented.

2.4 Software

Earlier developed control algorithms were written in assembly programming language but for a less advanced PIC micro-controller. Its main advantage was the small and efficient program coding.

In our project, C programming language is a much more cost effective alternative because it reduces the development time and produces more readable code even if it is larger.

The structure of the software is also fairly easy. The whole operation of the oximeter is controlled by two main functions. The first is responsible for the communications, the second for the measurements. Both of them still need further improvement but they are sufficiently developed enough to be tested.

2.4.1 Measuring function

According to the two different wavelength light sources in each period, eight measurements are carried out; four at 660 nm and four at 910 nm.

In any optical application, noise reduction is one of the most important challenges. In this case simple averaging is used.

On one hand, averaging can be easily realized and works well when samples are within a range of $\pm 3\%$. On the other, it is extremely sensitive to out of range values. One of these situations is represented by Fig. 10.

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Oximeter Evaluation Board V1.0
PIC18FL2420 Platform, Receiver Side
V1.0 Integration, 2007

ADresNIR01: 352
ADresNIR02: 352
ADresNIR03: 352
ADresNIR04: 0
Average: 264
Press a key to continue!
    
```

Fig. 10. Disadvantage of averaging

2.4.2 Upgrading noise filtering

To avoid future complication and measurement failures an additional filtering method has been implemented with marked success (Fig. 11).

In the graph below two different averages can be seen. The first one is simply calculated from the four samples. If, as in this case, one sample highly diverges from the other three then the average will be miscalculated.

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*****
Oximeter Evaluation Board V1.0
PIC18FL2420 Platform, Receiver Side
V1.0 Integration, 2007

ADresNIR01: 352
ADresNIR02: 352
ADresNIR03: 352
ADresNIR04: 0
Average: 264
The new FINAL AVERAGE: 352
Press a key to continue!
    
```

Fig. 11. Additional filtering

Therefore to avoid any miscalculation an outside value filter has been developed. This filter calculates the distance of the samples from the average and the sample with the biggest difference is disregarded, afterward a new average calculated from the three remaining measurements.

The differences between the two methods are illustrated by Fig. 12.

2.5 Accuracy of the A/D converter

More than seventy voltage levels (0..1.65 V) were converted by the A/D converter. Output values (0..1023) of the A/D converter were also associated with voltage levels and then compared to original input levels. Each of these values is averaged by five measurements.

The results were impressive. The relative error rate of the converter was 0.2 % in full scale. From a different aspect the error was 1 LSB as stated in data sheet [4].

2.6 Results

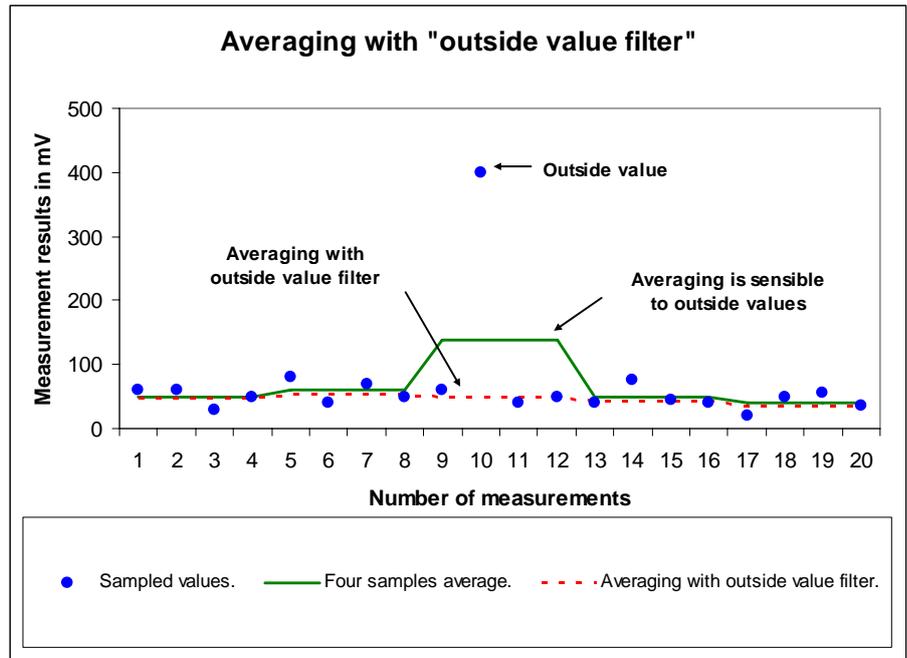
Although our most recently developed oximeter needs some further improvements, the enhancements which have been achieved are remarkable:

- A new evaluation board has been designed and engineered based on new miniaturized components and architecture
- The control software has been implemented to the new architecture, evaluation board and C programming language
- Both the bases of the measuring and communication functions are operating effectively
- Due to the new reduction filter the measurements are more accurate than ever before.

3 Conclusion

According to the experimental results set out above, a small-sized PWB (Printed Wiring Board) has been designed and produced (Fig. 13.). The hardware is completely ready for testing under field conditions. We also give ideas about the fastening and coating of the oximeter. The user friendly interface - a stable beta version - and the Matlab based software have also been improved to provide more accurate measurement results.

Fig. 12. Comparison of different noise filtering



The project is close to producing a full-featured, miniaturized, wireless, non-invasive pulse oximeter which is smaller and more comfortable both for the mother and for the obstetrician than any other solution available at present. We believe that the most important feature of our device is that it is completely harmless to the fetus.

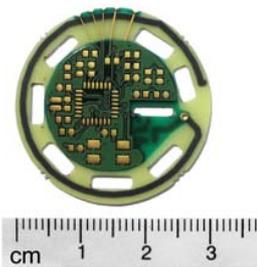


Fig. 13. Final size of the oximeter PWB

4 Further Issues

More experiments are needed to determine the optimal power of the light sources and the optimal distance between the light sources and the photodiode. Another important topic of future research is to determine the optimal force which needed to be applied to fasten the equipment. According to the results the accuracy of the measurements can be improved.

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- 7 Fig. 5. Internal fetal monitoring.
Source: <http://www.answers.com/topic/fetal-monitoring?cat=health>.
- 8 Fig. 7. Accurate position of Nellcor® oximeter
Source: <http://www.moberg.com/files/gallery/OxiFirst.htm>.