CONSTRUCTION OF A WIRELESS FETAL PULSE OXIMETER

SUMMARY OF PHD THESIS

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PRELIMINARIES – PULSE OXIMETRY

Pulse oximeters are devices commonly used in clinical practice. With their help the oxygen saturation can be measured in arterial blood with an error of 1-2%. Pulse oximeters are capable of non-destructive and continuous measuring, in other words, they are non-invasive devices.

By measuring the arterial blood oxygen level, a possibly arising condition of reduced blood oxygen content, medically known as hypoxemia can be diagnosed.

Thus, pulse oximeters are basically measuring devices promoting the diagnosing of the lack of oxygen. In medical practice, pulse oximeters are used for surveillance of patients in a number of cases: in anaesthesia, in obstetrics and during labour, in emergency intervention, during surgical operations and in case of cardiovascular problems or pulmonary diseases. They are also frequently used in hospital rooms, in patient transport, in ambulances and in newborn wards, as well. In case of pulmonary diseases, when the oxygen uptake capacity of the lungs is decreased, the pulse oximeter may be utilised to determine the seriousness of the disease, to assess the efficiency of the applied therapies or to adjust the quantity of oxygen artificially dosed for the patient.

Fetal pulse oximeters are among the advancements of medical electronics of the past 15 years. This instrument allows the arterial oxygen saturation of the fetus to be monitored during labour and delivery in a way independent from the mother's body. Childbirth is one of the riskiest periods in our lives. Several birth defects may occur in case of any childbirth. Most of these can – if recognised in time – be treated by modern medicine.

Without a fetal pulse oximeter, blood oxygen level cannot be monitored non-invasively reliably, which reduces the chance for birth complications to be recognised in time. However, conventional fetal pulse oximetry still has several problems to be overcome.

THE PROBLEMS OF THE RESEARCH FIELD TO BE RESOLVED

Due to the difficulties of fetal monitoring, fetal pulse oximeters did not spread widely. The fetus is located in the abdomen of the mother, isolated from the outside world. The measuring head of the fetal pulse oximeter has to be in contact with the skin surface of the fetus. Therefore, research in a real environment, as well as, testing and development of fetal pulse oximeters are a rather circumstantial task:

- They require medical expertise;
- strict directions of hygiene have to be observed,
- they are subject to licensing,

- they involve a certain degree of risk for both mother and fetus, and
- the period represented by the few-hour phase of the labour is limited.

Pulse oximeters are calibrated with an invasive method. Oxygen saturation of arterial blood is measured on hundreds of volunteers with arterial catheter and blood gas analyser, and the ratio *R* physically measured by the new oximeter construction is simultaneous monitored. The procedure is circumstantial:

- due to its invasive character it requires medical expertise and supervision and also involves a certain degree for the volunteers,
- it is lengthy because of the large number of subjects needed
- the needed instruments are expensive,
- the procedure is expensive.

The value of ratio *R* is in itself much less informative than the absolute value of oxygen saturation. During the development of pulse oximeters, it would be very useful if developers could see the absolute value of the oxygen saturation measured by the oximeter already at a prototype level:

- the value displayed by the oximeter would appear in a SpO_2 percentage, in an objective form unambiguous for everyone,
- fluctuations caused by noise would be easier to observe,
- a fluctuation of measured values arising from some possible failure in prototype planning or assembly would have a more conspicuous form,
- comparative measurements between the various subjects could be rendered more expressive.

The conventional pulse oximeters are catheter based. The lengthy measuring head is applied in the initial phase of labour through the birth canal, when the amniotic membranes are already ruptured and the cervix is dilated to 3 centimetres at least. The catheter is attached, by being pushed through the birth canal and the cervix, between the fetus' face or the top of his/her head and the wall of the uterus which gives the measuring head a more or less secure position. The sensor head fastened to the fetus' head is connected to the display unit located in the labour room with a cable (catheter). Labour is painful for the mother, therefore, the woman in labour is always striving to assume the position which is the least painful. This involves continuous movement. The measuring cable of the conventional fetal pulse oximeter hinders the movement of the woman in labour.

The length of the labour may in many cases reach 8 to 10 hours. During the labour, the measuring head often slides aside; in that case the measuring head needs to be repositioned. This causes further inconvenience.

In sum: the common drawback of catheter based, conventional fetal pulse oximeters is the presence of the measuring cable (catheter).

- Because of the presence of the lengthy measuring head and catheter it causes discomfort to the woman in labour.
- Because of the cable connecting the measuring head with the display unit the free movement of the woman in labour is hindered.
- Because of the movement of the fetus and the mother, the measuring slides aside during the labour. In such a case the measuring head needs to be repositioned through a brief medical intervention.

OBJECTIVES

The aim of my dissertation is to give a state of the art description of the field of pulse oximetry, encompassing adjoining areas as well.

In addition, my aim was to examine scientifically various problems arising in the field of fetal pulse oximetry and elaborate the possible solutions.

Objective 1.

Starting out from the difficulties described above, my set objective in this dissertation was to design and construct a fetal phantom, with the help of which the parameters of fetal tissue structure and circulation could be simulated, making it possible to replace the circumstantial pulse oximeter testing in real environment as well as to conduct fetal pulse oximetry research also outside the obstetrical ward. The phantom is an artificial element of the measuring system which has characteristics similar to the real body part or tissue, from the aspect of the given experiment, emulating them.

The various parameters of circulation (pulse, pulsation strength, diameter of arteries) could be variable with the phantom, allowing the examination of the pulse oximeter with the phantom placed on it in a broad range. The relatively constant parameters of a live fetus would not make this possible.

A further aim of the fetal phantom construction was to examine the impact of low fetal pulsation on the in-house built pulse oximeter (to be defined later on) intended for fetal monitoring, and to verify thereby that the pulse oximeter is suited, despite the weak fetal pulsation strength, for detecting fetal pulsation and for measuring the ratio R necessary for the calculation of the oxygen level.

Objective 2.

I set as an objective to elaborate a non-invasive calibration procedure for pulse oximeters which requires no blood sampling and overcomes the drawbacks of invasive calibration, as well as, its substantiation by measurements. By means of the procedure, a pulse oximeter under development can be calibrated much more simply and inexpensively than with the invasive method, thus, it becomes capable of determining the SpO_2 value on the basis of ratio *R*. The drawback of the method is the higher inaccuracy in comparison to invasive calibration, because the inaccuracy of the reference device added to that of the calibrated one.

Objective 3.

In case of wireless measuring systems it is favourable, from the aspect of energy consumption, if the processing and the evaluation of the measured signal does not take place in the battery-powered measuring head but on a high calculation capacity evaluation unit irrelevant from the aspect of consumption, (e.g., on a PC). However, this principle has not been applied in case of pulse oximeters having appeared up to now.

My purpose was to demonstrate, on the basis of calculations supported by theoretical data that the energy consumption reduction principle outlined above is also applicable in case of wireless pulse oximeters and a consumption reduction can be achieved with it.

Objective 4.

In order to resolve the above problems posed by conventional fetal pulse oximeters, I set myself the objective of constructing a new, compact, miniature, wireless pulse oximeter suited for fetal monitoring. With the construction of the device, the source of the above problems, the catheter could be eliminated. The pulse oximeter would be attached to the fetus' head with a simple medical intervention at the beginning of the labour. After this, it would be capable of measuring the fetus' blood oxygen saturation and pulse as long as even eight hours. It would transmit the measured data through radio frequency to the external display unit which is located in the labour room.

The new pulse oximeter would be easier to handle for doctors and more comfortable to wear for mothers in labour than conventional devices. Its spread might reduce the number of unnecessary caesarean sections, increase the ratio of healthy born infants, and thereby render childbirth safer.

In addition to the oxygen saturation and the pulse, the new oximeter would be capable of measuring the temperature of the fetus as well, which none of the other fetal oximeters is capable of. These features may render the device a fundamental pillar of fetal diagnostics in the course of labour and childbirth.

NOVEL SCIENTIFIC RESULTS

Thesis group 1.: Construction and validation of a fetal phantom

Related publications: [L1]

T1.1

On the basis of anatomical data published in the literature, I have constructed a fetal head phantom representing the fetus' head area around the posterior fontanelle with variable parameters. Thereby I have implemented a new instrument and elaborated a new method for the examination of the impact of weak fetal pulsation on pulse oximeters. In the phantom, the strength of heart beat, the pulse rate and the artery diameter are adjustable. The phantom is capable of simulating a pulsation strength characteristic of the fetus for the pulse oximeter attached to it outside hospital environment, thus, it can be a useful instrument of pulse oximetry research and of the development of pulse oximeters.

T1.2

With the help of a simulation working with ray tracing based on Monte Carlo method, I determined the change of the intensity of light getting into the detector of the pulse oximeter attached to the fetal head phantom defined in thesis 1.1 depending on pulsation strength. In case of an artery diameter of 0.4 mm a pulsation strength of 8 % causes a change of 0.82 % in the intensity of photons getting into the detector.

T1.3

On the basis of measurements with a pulse oximeter on a fetal phantom detailed in Thesis 1.1, I determined the change in the intensity of photons getting into the detector of the oximeter depending on pulsation strength. The parameters of the light-source of the oximeter's detector were identical with the data used in the simulation. The value of the change in the intensity of photons getting into the detector was 1.2 %, in case of an artery diameter of 0.4 mm and a pulsation strength of 8 %.

By collating the results of the simulation and of the measurements I verified that the prepared fetal head phantom has parameters similar to those of the real fetal head from the aspect of pulsation strength and tissue structure.

Thesis group 2.: Elaboration of a non-invasive calibration procedure

Related publications: [L3, N5]

T2.1

I elaborated a non-invasive pulse oximeter calibration procedure which requires no blood sampling and which is more simple and cheaper to construct than the invasive method. During calibration, the pulse oximeter under calibration is attached to the subject and measures the ratio *R*, while a calibrated pulse oximeter simultaneously measures the subject's SpO_2 value. The blood oxygen saturation of the subject gets reduced by the inhalation of artificial air while the measured values of *R* and SpO_2 are recorded. On the basis of the value pairs received, the function between *R* and SpO_2 can be determined.

T2.2

I have verified the method detailed in Thesis 2.1 with a practical series of measurements. With the method described, I determined, on the basis of a series of measurements performed on 9 healthy adult subjects the calibration chart of a wireless pulse oximeter prototype, that is, the relationship between the measured ratio *R* and the real SpO_2 value in the range between SpO_2=86-100 %. In addition, I proved, through linear and second-degree regression analysis, that the received relationship can be linearly approached in the above mentioned range with a negligible error

Thesis group 3.: The principle of the reduction of consumption

Related publications: [L2]

T3

Based on theoretical calculations, I demonstrated that the principle of the reduction of energy consumption, the essence of which is that the data evaluation does not take place in the battery powered measuring head but on an external evaluation unit irrelevant from the aspect of energy consumption, (e.g., on a PC), is also efficiently applicable in case of wireless pulse oximeters. By applying the principle, energy saving of 41 % can be achieved. I verified the accuracy of the parameters in the calculation through a current measurement performed on a pulse oximeter constructed on the basis of the principle.

Thesis group 4.: Construction of a wireless fetal pulse oximeter

Related publications: [L1, N1, N2, N3, N4, N6, N7, N8, N9]

T4.1

I have set up a system of criteria of miniaturization, which makes it possible to construct a measuring head smaller than all others until now. The system of criteria consists of the following three elements.

1. Placing the measuring head (consist of the LEDs and the photodiode) on the same printed circuit board as the measurement control and the signal conditioning electronics. Integrating all electronic elements that are necessary for the measurement of blood oxygen level based on the principle of pulse oximetry onto one single printed circuit board, including the radio, the microcontroller controlling the measurement, the ASIC chip (with the analogue electronics) and the battery as well.

2. Integrating all analogue electronic elements into one single ASIC chip which results in a significant reduction of size.

3. A conformal coating (with a thickness in the range of hundred micrometers), which provides 100 % protection against water penetration and compact set-up, as well as, supersedes the conventional casing greatly enlarging the dimensions of the instrument.

T4.2

Making use of the principles and methods detailed in Thesis group 2 as well as in theses 3 and 4.1 I have constructed a novel, miniature, battery powered, reflective type, wireless arterial blood oxygen level measuring system. The device is capable of monitoring the plethysmographic curves on two wavelengths and of determining the arterial blood oxygen level and pulse rate from it. The physical dimensions of the device (23.1 mm PCB diameter) would make fetal monitoring in the birth canal possible as well.

T4.3

I attached an in-house developed pulse oximeter, operating on the basis of principles described in thesis 4.2, to the fetal head phantom detailed in Thesis group 1. I performed a series of measurements with the pulse oximeter for various artery diameters and pulsation amplitudes characteristic of the fetus. I ascertained that the pulse oximeter has sufficient sensibility even in case of weak pulsation values characteristic of the fetus, for measuring the ratio *R* necessary for the determination of the oxygen saturation of arterial blood.

LIST OF PUBLICATIONS RELTED WITH THE THESES

Peer reviewed journal papers

[L1] Stubán N., Niwayama M.: Adjustable fetal phantom for pulse oximetry, Review of Scientific Instruments, Vol. 80, Issue 5, 2009, DOI:10.1063/1.3131632

[L2] Stubán N., Harsányi G.: Reducing power consumption of wireless pulse oximeters, Sensor Review, status: under review

[L3] Stubán N., Niwayama M.: Non-invasive calibration method for pulse oximeters, Periodica Polytechnica, accepted for publication, expected publication date: 2009.

Non peer reviewed journal paper

[N1] Stubán N.: A magzati véroxigénszint mérés új lehetősége, Elektronikai Technológia, Mikrotechnika, accepted for publication

Hungarian patent announcement

[N2] Stubán N.: No. P0900329 hungarian patent announcement. The title of the patent will become public after 18 month from the announcement. Date of the announcement: 2009.05.27.

International conference papers

[N3] Becker Á, **Stubán N.**, Harsányi G.: Construction and First Experimental Results of a Wireless Fetal Pulse Oximeter, International Symposium for Desgin and Technology of Electronic Package – 14th Edition (SIITME 2008), Brasov, Romania, pp. 247-252.

[N4] Stubán N., Sántha H.: New way in fetal monitoring: wireless fetal pulse oximeter, Inter-Academia 2008, Pécs, Hungary, 2008. September 15-18., pp. 482-489. ISBN: 978-963-420-963-8

[N5] Stubán N., Sántha H., Niwayama M., Yasuda Y.: Evaluation of a compact wireless pulse oximeter, Inter-Academia 2007, Hamamatsu, Japan, 2007 September 26-30, pp. 123.

[N6] Stubán N., Sántha H.: Miniaturization concept of pulsoximeters, Inter-Academia 2006, Iasi, Romania, 2006. September 25-28., Vol 1., pp. 303-314.

[N7] Stubán N., Using photons to diagnose and monitor diseases, Ninth International Symposium on Contemporary Photonics Technology (CPT-2006), Tokyo, Japan, 2006. January 11-13, pp. 91

[N8] Stubán N., G. Harsányi, H. Sántha: Two development concepts of non-invasive oximeters, Surface Mount Technology Association - Medical Electronics Symposium (SMTA-MES), Minneapolis, USA, 2006. May 15-17.

[N9] Stubán N.: Design and implement non-invasive, reflective blood oxymeter, Intrnational Symposium for Design and Technology of Electronic Packages (SIITME 2004), Bucharest, Romania, 2004. September 23-26, pp. 179-183

FURTHER SCIENTIFIC PUBLICATIONS

Hungarian patent

[N10] Sántha H., Harsányi G., **Stubán N**.: Mikrofluidikai szinteltolásos csatorna és eljárás a megvalósítására, valamint e szinteltolásos csatornát tartalmazó mikrofluidikai rendszer, Patent number: P 07 00670, Disclosure date: 2009.

International patent announcement

[N11] Sántha H., Harsányi G., **Stubán N.:** Microfluidic channel, method for its implementation, and microfluidic system containing said channel, , Patent number: WO2009047573 (A1), Disclosure date: 2009-04-16

Non peer reviewed journal paper

[N12] Stubán N.: Analóg és digitális áramköri elemek közös hordozón – tervezési megfontolások Elektronet, 2005/7. November pp. 70-71., 2005/8. December pp. 73-74.

International conference papers

[N13] Sántha H., **Stubán N.**, Harsányi G.: Design considerations of small size reflective type pulse oximeter heads in special applications, Electronics Systemintegration Technology Conference (ESTC 2006), Dresden, Germany, 2006 September 5-7, pp. 404-408.

[N14] Stubán N., Wireless data transmission between Personal Computers, International Spring Seminar on Electronics Technology (ISSE 2004), Sofia, Bulgaria, 2004. May 13-16, pp. 237-241.