Abstract—Critically ill prematurely born babies admitted at the neonatal intensive care unit (NICU) have to be monitored constantly. The saturation of the peripheral oxygen (SPO2) is one of the crucial monitoring parameters on these babies. It is necessary that these fragile neonates feel most comfortable as possible during the monitoring. The current solutions for these SPO2 oximeters can be uncomfortable for use and hampers parent-child interaction. In this paper we propose an innovative solution for reflectance pulse oximeter based on Near Infrared Spectroscopy (NIRS) techniques that will lead into more comfortable use in a long term monitoring. Prototypes with the reflectance sensors embedded in soft foam and fabric materials are built to enhance a comfortable non-invasive yet reliable monitoring. These monitoring units give the opportunity of integration into a snuggle and mattress where the baby lays on most of the time. In this paper we report the integration of the prototype monitoring units into a snuggle. To evaluate the comfort as well as performance of the final prototype, we first conduct tests on adults. The prototype monitoring units are tested on various body locations of adult participants. Signal quality on different body locations is reported and questionnaires for comfort assessment are analyzed. Experiments on the premature babies will be carried out at NICU of Máxima Medical Centre (MMC) in Veldhoven, the Netherlands.

Keywords: Neonatal monitoring, Reflectance oximeter, Saturation of the peripheral oxygen, NICU, Design process

I. INTRODUCTION

Premature birth occurs in between eight to ten percent of all pregnancies in the developed parts of the world. Early birth of these neonates leads to severe health problems especially respiratory problems. Their lungs mainly but also other organs are not fully developed yet. Therefore these fragile babies have to be constantly monitored for urgent diagnoses and to prevent the collision of the organs and the organism as a whole by institution of the appropriate medical treatment. This constant health monitoring is proceeded at a neonatal intensive care unit (NICU) where the premature neonates are placed in incubators.

The saturation of peripheral oxygen (SPO2) is one of the key physiological processes to be monitored perpetually on these premature babies [1]. This physiological process assesses the percentage of arterial haemoglobin that is saturated with oxygen. Currently, the saturation of peripheral oxygen (SPO2) is monitored by a transmissive oximeter with the sensor unit attached on the foot or palm of the neonate [2]. The presence of the adhesive and all the wires can lead to discomfort, irritation and even painful stimuli especially when removing the sensor from a thin and very sensitive skin of the neonates [3]. Reflectance pulse oximeters, based on Near Infrared Spectroscopy (NIRS) techniques are attached on the forehead above an eyebrow have been developed [4]-[6]. The current design solution is however not the most comfortable one as to a presence of thick wires. It also does not give an option for changing the measuring location on the baby’s body.

Therefore we have been working on an innovative yet more comfortable solution for this smart monitoring technology. Optimizing the reflectance sensor, thorough choice of suitable materials and forms as well as incorporation of the electronic components into those is essential for a positive outcome from this design research. In this paper, we present and demonstrate the design solution that we came up with after several iterations and adult user tests. Signals obtained by the prototype on different body locations are analyzed. Comfort of the prototype is evaluated by subjective approach, for example questionnaires. Experimental findings from the adult user tests show a feasibility of measurements on a new and not yet explored location which is a side of a cheek. The findings inspire us to design a sensor unit that makes a connection with the side of a baby’s cheek. The sensor unit is a part of a snuggle in which the baby lies in an incubator. Overall this solution leads to new openings and a flexibility of measurements on different body locations.

Further experimental testing on neonates at Maxima Medical Centre (MMC) will be carried out for validating the monitoring performance and comfort of the proposed design.

II. DESIGN PROCESS AND DESIGN CONCEPT

A. Design Process

The aim of this innovative non-invasive design solution is to provide a higher comfort while monitoring the saturation of the peripheral oxygen when the neonate is inside the...
incubator. The first step towards the implementation of this non-invasive design solution is to design a product that:

1. Contains a reliable reflectance pulse monitoring device
2. Provides a high comfort for a long term monitoring
3. Gives an opportunity to place the monitoring device on different locations of a neonate’s body
4. Helps to sustain the medical staff workflow

Methodologies commonly used in Industrial Design field are applied in the design process of the innovative non-invasive design solution. Neonatal monitoring is a multi-disciplinary area which involves a unique integration of knowledge from medical science, design, technology and social studies. The iterative design process in Fig. 1, starts with initial research of the reflectance oximeter technology, medical science related to oxygen saturation and blood flow and full comprehension of different user profiles involved with the final product (neonates, medical staff and parents). Leading design requirements were derived from the information search, creating a strong base for developing several initial design concepts of the first iteration circle. These concepts included challenges in embedding the existing reflectance oximeter in soft cushioned materials compatible with electronics and medically proven at the same time. Aesthetics and functionality issues within NICU were also confronted. The initial ideas were compared (tested) by advantages and disadvantages in a field of electronics re-design, innovative perspective and overall feasibility. A design decision was made that resulted in one concept that set further design requirements and refinements. These were considerably translated into development of the final design concept (second iteration circle started). This concept would presumably be more suitable to the needs of the neonates, providing a reliable technology function and holding a great opportunity for the current NICU workflow. This latest concept should therefore meet the following requirements:

- Provide continuous and reliable SPO2 readings
- Offer highly comfortable solution of monitoring than the existing product
- Be safe to use at the NICU environment
- Help the workflow of the medical staff
- Gain the feeling of trust by the parents and medical staff by an attractive design
- The electronic units must be easy to detach for cleaning purposes of other parts
- The chosen materials for the electronic units must be suitable for alcohol cleaning
- Gives an opportunity to place the sensor unit on different parts of a body for future monitoring location options

Considering all the requirements as well as technology possibilities derived from the research a final idea was generated and developed further.

B. Design Concept

The resulting concept is a re-designed snuggle with SPO2 sensor unit embedded as shown in Fig. 2. The sensor unit could be positioned on the bottom of the snuggle, on the snuggling parts of the product as well as on an attached hat in the top area of the snuggle. These positions shall be finalized from the user tests for a quality of signal on different locations of the neonatal body. Re-design of the existing reflective sensor would be highly important to make the sensor as flattest as possible. Therefore use of flexible wiring would be a great advantage of the re-design, especially when a baby lies on top of the sensor unit. Also in this concept the choice of suitable materials is necessary, not only for the compatibility with the electronics but mainly to sustain a high comfort for a long term monitoring. Another criteria that would have to be fulfilled is the possibility of detaching the sensor unit for the cleaning purposes of the snuggle.

A prototype snuggle with the sensor unit is shown in the Fig. 3. The snuggle is a soft, cute looking nest with the SPO2 technology embodied to provide an acute and instant care for the prematurely born babies. The padded parts with silicon
beads inside of them gives a baby the gentle feeling of a touch as well as more practical support for positioning. The materials and their colour are carefully chosen so they sustain the baby’s comfort and healing. The sensor part can be detached anytime and alcohol wiped clean for the hygienic purposes. The snuggle can be washed on regular washing temperature without losing its shape.

Figure 3. Prototype snuggle with sensor unit

A. Sensor Unit Prototype

Based on the set up design requirements re-designing of the adult reflective sensor was necessary. The current electronic components were bulky in areas and contained thick wires. That leads to a discomfort and pressure sores. Therefore we developed a flex foil wiring for the sensor unit prototype. This dimension minimizing solution gave us an opportunity to develop a high standard sensor unit prototypes sustaining a great comfort. Three pairs of different sensor prototype sets in Fig. 4 (each pair with and without dome shaped cup over the sensor’s LED), were pre-designed for the quality of signal and comfort adult user tests. The new flex wire reflectance sensors were embedded within materials that met the set design requirements. The materials used were:

- Neoprene (Fig. 4(a),(b)) – it gives spongy-soft feeling as well as slight anti-skidding functionality to prevent the movement artefacts
- Natural rubber (Fig. 4(b)) – part surrounded by neoprene – the rubber provides a great anti-skidding property but it is hard at the same time
- Open cell foam (Fig. 4(b)) – placed underneath a patch of neoprene with the natural rubber part to soften the hard feeling of rubber
- Wool felt (Fig. 4(c) as contents) – it offers soft-to-touch feeling but is not suitable for medical purposes unless it is covered by an appropriate material
- Nylon base fabric (Fig. 4(c) as a cover) with polyurethane coating (PU cover) covering the wool felt provides anti-skidding functionality, hypoallergenic and medical authentication and alcohol cleaning possibility.

Figure 4. Three initial prototypes pre-designed for adult user tests

The signal quality evaluation of adult user tests (please see section IV. ADULT USER TEST) showed that prototype, using the black neoprene only, received more good quality signal readings than other prototypes. However prototype sets, using the wool felt as filling and PU cover, got the strongest signal readings out of all. These readings were noted especially on location where the sensor made a contact with the side of the cheek muscle. Prototype sets were also inspected from the comfort point of view. The prototype using PU cover and wool felt was evaluated as the most comfortable one. However the wool felt is not medically compatible therefore it was substituted with the neoprene that came straight after in the comfort test results. Therefore we concluded to use the combination of both prototype types employing the neoprene and nylon base fabric with PU coating for the final prototype, Fig. 5(a), shows the final prototype, which is designed to be placed on the bottom of the snuggle. Depending on which side the baby lays, the prototype is locate either on right or left side of the snuggle in the area where the baby’s cheek makes a connection with the snuggle. The final prototype of the sensor unit has a user-friendly round shape that also gives an option to be positioned on either left or right side of the snuggle. The electronics are embedded within the materials that gave us good results in the quality and comfort testing but also meet the requirements such as:
- anti-skidding for reducing of the movement artefacts
- electronic compatibility
- hypoallergenic and medical authentication
- alcohol cleaning possibility

Figure 5. The final prototype of the sensor unit

The methods of fabrication make an important role in producing highly comfortable product. We therefore propose a solution of sewing the edges of the PU cover so that the edges decline gradually to provide smoother transition of the edges to the snuggle surface to accommodate higher comfort for the neonates. The option of repetitive detaching of the
sensor unit from the snuggle is facilitated by adding a Velcro patch on the back of the sensor unit (Fig. 5(b)), and on the bottom of the snuggle (Fig. 5(c)).

B. Snuggle Prototype

The shape of the proposed snuggle prototype Fig. 6, is more or less the same as the existing one. However we propose to add another snuggling part on the top of the snuggle. Both of the snuggling parts, one on the bottom and one on the top of the snuggle are filled with grainy like material. The structure of the material provides the flexibility of the snuggling parts to be folded around the curvy areas of a neonatal body. Its weight also gives a modest pressure onto the baby’s skin so the baby feels touched, hugged or cuddled. The materials used for the snuggle prototype are printed cotton, white cotton, polyester fibre wadding and elastomer silicon beads to fill the snuggling parts. All materials are medically proven.

Determination of the overall snuggle size and positioning the sensor unit to the correct location was determined from an ergonomics literature [7]. Added design feature in sense of embroidered graphics gives an option to reposition the sensor unit according to the length of the baby. It clearly shows where to position the sensor unit so no mistake can be made by medical staff and their work-flow is undisturbed. We propose three different sizes of the monitoring snuggle, S, M and L.

IV. ADULT USER TEST

We conducted tests on adults first to make sure the prototypes are safe to use and function well, before testing on neonates. Tests on comfort of mechanical design incorporation of SPO2 reflectance sensor and quality of the measurements on different parts of a user body were performed. The aim of this study is to mechanically incorporate the existing SPO2 reflectance sensor technology in thoroughly selected soft materials so it will provide a high comfort to the user as well as reliable readings at the same time. In this section, the testing procedure and evaluation are explained.

A. Testing Procedure

An investigation of these sets of design has to be implemented to receive data of different levels of comfort as well as reliability of the readings on different parts of a body (mainly torso and head). For this application a pre-designed SPO2 reflectance sensor sets are used to check the reliability of the readings. The pre-designed SPO2 reflectance sensor is placed on the trapezius muscles, back of the head and neck, upper part of an arm, back side of a shoulder, back of the neck, side of a chest, above an eyebrow and on the side of a cheek. The location when the sensor makes a connection with the back of the head was discarded as the amount of hair would probably make a significant difference in the quality of the signal. This location would however be suitable for the neonates that do not have much amount of hair grown yet.

The tests were conducted on five healthy participants whose age ranges from 20-40 years old; there were two women and three men participating. Calibration was carried out on the monitoring system for the pre-designed sensor units, and inspections of the signal reliability on an adult finger tip was performed before each measurement.

There were three pairs of different prototype sets as shown in Fig. 4 to test on seven different locations without and with a presence of a thin layer of cotton. Each sensor set was positioned underneath of each location. A participant laid on the sensor unit calmly. The weight of a body made a natural pressure to the sensor and the connection was made. The signal quality was thoroughly logged for each sensor set, location and a presence or absence of a thin cotton layer. The comfort of the sensor prototype sets is measured by answering pre-formed questionnaires for the participants during the testing procedure. The examples of questions are:

- How do you feel the current prototype on your skin?
- Do you feel any sore pressures from the current prototype?
- Is the current prototype soft or hard to the contact with your skin/tissue?
- Is the prototype overall comfortable for a long term use?
- Can you rank the prototypes from the least comfortable to the most comfortable?
- Please state the reason why you think this one is more comfortable than the previous one.

B. Evaluation of the Adult User Tests

All signal processing and feature extraction was generated by MatLab R2010a software that was determined as an optimal evaluating tool. Fig. 7 (a) shows one of the generated good photoplethysmography (PPG) signal. The condition of the PPG signal waveform was primarily determined by visual inspections by a PPG expert. All the visual inspections were then logged in a log book and noted appropriately as whether there was observed:

- no signal,
- irregular signal,
- regular signal with a noise (possibly present due to breathing artefacts),
- or good signal.

Figure 7. Side of a cheek bone good PPG signal waveform

An example of one of these log book entries is illustrated in Fig.7 (b). Choosing an inspected data with a good PPG signal (line No. 16, 17) the indications are as follows:

- “sub2” means subject 2,
- “loc8” means location where the sensor makes a connection with a place on the side of a cheek (laying with a head on the sensor set – on a stomach),
- “protoA” is a prototype with labelling A (sensor unit incorporated in Neoprene material, LED/IR of the sensor without a presence of a dome shaped cup)
- “WoCo” or “WthinCo” meaning without a cotton layer or with a thin cotton layer.

As seen from the presented example a good PPG signal quality was established on the location on the side of a cheek.

From the overall inspection of the signal strength and quality we came to a conclusion that in most cases we received a good quality signal on the location where the sensor made a connection with the side of the cheek. The presence of the dome shaped cup in the prototype sets with double labelling might give us a better quality of signal but it varied a lot therefore we were not able to come to one direct conclusion. This measuring requirement would have to be further investigated. Also the test requirement whether we obtain a same strength and quality of the signal with using a thin layer of cotton cannot come to one final conclusion. And that is because the signal varied a lot throughout whole measurement. However overall we presume that direct contact of the sensor with the skin gives much better results than with a thin layer of cotton. This measuring requirement can be further investigated. During applying the prototype sets on the side of a chest we found out that a better signal between two ribs can be obtained rather than on the bony area of a rib. However from the signal evaluation we came to a conclusion that this location is not suitable for monitoring because the presence of breathing is disturbing the quality of the signal. We also registered that when we applied the prototype sets on the muscular area of the cheek just below the cheek bone on the front side of a face, we did not obtain such a good quality of the signal as when we moved the sets on the side of the cheek, on the edge between the front of the face and the area close to the ear. But also it was very hard to find the correct area as there were many irregular signals until we received a quality signal suitable for logging in. Therefore we suggest placing the oximeter part of the prototype on the side of the cheek just below the cheek bone but not on the chunky area and also not too close to the ear area, as shown in Fig 8.
It might be however difficult to detect this exact area on a neonate’s petite face during the NICU workflow therefore we suggest further clinical tests on neonates that will show whether this entire area is suitable for monitoring at all. The results of the proposed clinical tests might also show that the monitoring area can be larger due to better conductivity of neonatal skin to a reflectance pulse oximeter technology. If such results will arise problem with positioning of the sensor unit would be overcome.

The evaluation of the pre-formed questionnaires for the comfort of the prototype sets was also performed. By analyzing the answers prototype sets containing the wool felt and PU cover was stated as the most comfortable from all the prototypes. However prototype sets made out of neoprene only was described as the one with very good anti-skidding properties. It was noted that the edges on all prototypes should be smoothed out to provide a high comfort. According to the signal quality evaluation prototype made out of neoprene only received the most signal quality readings out of all prototypes, but prototype sets using the wool felt and PU cover obtained the strongest signal out of all, especially on the side of the cheek bone. Therefore we suggested using the combination of these two prototype sets for the final prototype and next user tests that will be performed on prematurely born babies of 30-32 weeks of gestational age. We presume that such combination of soft materials will be more non-invasive and comfortable for the neonates especially when compared with the current invasive oximeter solutions that lead to painful stimuli.

V. DISCUSSION AND PROPOSAL

The discovery of a new monitoring location, the side of a cheek, was remarkable. This aspect is giving great chances for future research and development of innovative products in the health care field. However it has to be remembered to keep the sensor unit on a correct location due to the signal reliability and to prevent high discomfort from unexpected shining into eyes. At the present the snuggle prototype is ready for clinical testing within the MMC. However the final prototype holds many possibilities for even finer development. For instance, the detaching mechanism of the sensor unit should be reconsidered to provide more robust measurements against motion artefacts.

The outstanding findings of the adult user tests and demonstration of the prototype were shown to the personnel of the NICU at MMC. Positive feedback was obtained directly from the NICU head nurse that confirmed the novelty and possible larger comfort of the snuggle and its sensor part for the neonates. She also positively highlighted the colour choice and snuggling parts of the snuggle that will provide a hugging feeling to the neonates. Dr. Sidarto Bambang Oetomo (NICU specialist at MMC) is currently supporting the overall arrangement of approval for the clinical testing on neonates.

VI. CONCLUSION

In this paper, we proposed an innovative and comfortable solution for monitoring of neonates using reflectance pulse oximeter. The process consists of concept generation, optimizing the reflectance sensor, incorporation of the electronic components, material selection, prototyping and evaluation. We demonstrated the final prototype with special designed sensor unit embedded into a snuggle. Experimental results on adult testing were reported for signal quality evaluation on different body locations and comfort assessment of the prototype. Based on the first reactions of the medical staff, the conclusion can be drawn that part of the user groups are positive about the first results. When the clinical tests in NICU, MMC Veldhoven are proceeded, it will provide us with more detailed conclusions and options for further development. This research is part of a larger project running at different TU/e research departments in corporation with MMC and Philips Research that focus on developing an overall non-invasive smart monitoring support for the prematurely born neonates. We believe this research and findings concluded from it will contribute to the future development of overall neonatal project.

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REFERENCES