Automated closed loop controller of inspired oxygen system for improved mechanical ventilation in newborns

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Abstract - Paper itself describes operation principles of mechanical ventilator, it's electronic and pneumatic solutions, as well as wide spectrum of advantages for patients that are coming with this technology. Special emphasis is placed on new technology in mechanical ventilation, where unlike before when nurses and doctors were constantly monitoring and adjusting O2 levels delivered to newborn / neonate by ventilator, automation of this process, using "The closed loop controller of inspired oxygen system (CLiO2), offers opportunity for better care of neonates.

We will display methods where CLiO2 system noninvasively and continuously measures the oxygen level in a newborn's blood using Masimo SET® Measure-Through Motion and Low Perfusion pulse oximetry technology to provide accurate and saturation of peripheral oxygen (SpO2) measurements, even under challenging clinical conditions. Paper describes that the CLiO2 system processes blood oxygen saturation levels by a computer algorithm that then anticipates trends and modifies the amount of oxygen delivered.

It will be shown how this system helps reduce complications associated with newborns needing mechanical ventilation and can free up time for clinicians to better care for some of their most vulnerable patients.

I. INTRODUCTION

Mechanical ventilators are rather complicated piece of machinery [1]. This is due to demanded high precision in gases delivery and multiple redundant and backup systems that ensure safety for patients. Basically, mechanical ventilator is a pump that will force gas mixture into patient’s lungs when patient itself cannot breathe for some reason (deep anesthesia, different injuries, etc). It consists of pneumatic and control modules. Pneumatic part usually consists of four main sections: pressure/flow generator (turbine), exhalation system, safety system and gas mixer - blender.

Control system consist of various safety and alarm systems, user interface with all available controls (touch screen is standard), various interfaces for external networking and power supply unit with battery backup system.

Neonatal ventilators are special ventilators with augmented all demands as on adult ventilators. Just imagine what kind of precision is needed to deliver just two millilitres of gas to neonatal patient [4] - [6], [8].

The other thing to deliver precisely is air (or heliox) and oxygen mixture in order to maintain proper saturation of oxygen in premature's blood. On older systems, it was pure mechanical adjustment of delivered oxygen. Oxygen percentage was adjusted via dial knob by doctors and nurses and monitored by electrochemical cell built into ventilator.

CPU was controlling blender solenoids and needle valves so proper mixture was achieved. Mixed gas was accumulated in gas accumulator, and from there, sucked in turbine via fine particle filter and then, through turbine and next filter delivered to patient. After it, inhalation [2] was driven out from patient through exhalation valve. There was no possibility to monitor blood oxygen saturation directly on ventilator, it was mandatory to use external saturation monitor. Saturation was constantly monitored by clinical staff and the fraction of inspired oxygen in a gas mixture (FiO2) was constantly adjusted in order to maintain desired oxygen saturation. Because of gas accumulator in respirator [3], there was certain amount of time needed until gas mixture reaches new concentration and get delivered to patient. During this time, patient is i.e. in hypoxemia and that can be very dangerous for premature babies, can cause irreversible brain damage and other clinically proven consequences. When clinician finally set new increased FiO2 in order to increase newborn's saturation [7], it takes time for gas mixture reaches higher concentration. After hypoxemic episode is finished, clinician again turns controls down to baseline FiO2 but still, in gas tank there is richer mixture that needs some time to decrease O2 concentration according to set control, which is delivered to patient. This enriched gas mixture can now cause hyperoxemia, which is dangerous as well [9]. If newborn in need of mechanical ventilation have 3-4 hypoxemic episodes in 24hrs period, it is easy to calculate risks and dangers coming from oxygen therapy.

New system developed made all this history. For first time, a closed loop controller of inspired oxygen, called „CLiO2“, was introduced [10].
II. THEORY OF OPERATIONS

Closed loop controller of inspired oxygen system was implemented in order to maintain proper saturation of oxygen in newborn's blood. Simplified diagram of this system is presented on figure 1.

Figure 1. Simple diagram for CLiO2 system

Baseline saturation is set by doctor and represents saturation they like to maintain as much as accurate.

The CLiO2 system noninvasively and continuously measures the oxygen level in a newborn’s blood using Masimo SET® technology to provide the most accurate and reliable oxygen saturation (SpO2) measurements. CLiO2 system processes blood oxygen saturation levels by a computer algorithm that then anticipates trends and modifies the amount of oxygen delivered. If necessary, adjustments can be made on a second to second basis, something not currently possible with manual control. The figure 2 shows how CLiO works.

Figure 2.  Algorithm targets the midpoint of the user set boundaries [5]

The Automatic FiO2 control system comprises three basic systems:

- Pulse Oximetry
- Control Algorithm
- Gas Delivery

Data is read continuously from the pulse oximeter module mounted on the respirator, and the SpO2 and heart rate are displayed on the UIM. The control algorithm receives updated SpO2 measurement data and calculates the appropriate FiO2 once per second. This value is then transmitted to the gas blender.

The control algorithm is a feedback loop component of the entire system. The algorithm compares the patient’s SpO2 to that of the set value (the midpoint between the high and low SpO2 Targets). The algorithm uses this difference (or “error”) to set the FiO2.

The algorithm makes immediate FiO2 changes to address the error, “learns” from past changes, and anticipates short term changes. These three tasks make up what is called a proportional integral derivative controller (PID controller). There are four factors that the algorithm responds to in order to determine what FiO2 should be delivered:

- The difference between the target and actual SpO2;
- The rate at which the SpO2 is changing;
- The range the patient is in (hyperoxemic, normoxemic or hypoxemic) as defined by the set high and low SpO2 targets;
- How long the actual SpO2 is “out of range”.

During periods of hypoxemia (SpO2 is lower than the Low SpO2 Target value), there is a rapid increase in FiO2 within 10 seconds of detection of hypoxemia. There will be a continuing rise in FiO2 while hypoxemia persists.

The rate of FiO2 increase is proportionate to the magnitude of hypoxemia. Changes in FiO2 are proportionate to FiO2 baseline (a running average of the FiO2 under steady conditions). In periods of normoxia (SpO2 is between the low and high SpO2 target values), if the SpO2 is stable and remains above the set value, but in the targeted range, there is a gradual weaning of FiO2 downward. If the SpO2 is below the set value, but remains in the targeted range, no further decreases will occur.

During hyperoxemic states (SpO2 is greater than the High SpO2 Target value), the controller decreases FiO2. Depending on the extent of the hyperoxemia, this reduction commences within 15 – 90 seconds, and leads to an increased and sustained reduction in FiO2 while the patient remains in the hyperoxic state.

During CLiO2 activity, gas accumulator in respirator is bypassed in order to improve response time and decrease lag, so gas is delivered directly from blender. If gas accumulator is not bypassed, there will be increased time for increasing or decreasing O2 level in gas mixture, so response time will be much greater.

III. HARDWARE AND SOFTWARE

Hardware implemented in this groundbreaking technology consists of two parts. Besides hardware implemented in respirator and necessary pneumatics which will provide CLiO2 functionality, most important
part is Masimo SET® MS 11 SpO₂ module. This newly developed ultra low power signal extraction pulse oximetry board utilizes only 125 mW power consumption while delivers unmatchable reliability and low perfusion performance.

Full ranges of single use self adhesive and reusable sensors are compatible with this board.

As precise and reliable saturation measurement is essential for flawless performance of ClO₂.

Masimo SET pulse oximetry is a new and fundamentally distinct method of acquiring, processing and reporting arterial oxygen saturation and pulse rate.

As illustrated on figure 6, Masimo SET technology enables the power of adaptive filters to be applied to real-time physiologic monitoring by utilizing proprietary techniques to accurately establish a “noise reference” in the detected physiologic signal, thus enabling the direct calculation of arterial oxygen saturation and pulse rate.

The conventional "red over infrared" approach measures the differential optical density of red (ο) and infrared (IIR) light as projected through a vascular bed and calculates a ratio (r) of the optical densities. Utilizing the optical density ratio, an arterial oxygen saturation (SpO₂) value is empirically reported based on the ratio obtained [11].

During routine patient motions (shivering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio based oximetry system. Having identified the venous blood as a significant contributor to noise during motion, it follows that if the noise reference corresponding to the venous component could be measured, then an adaptive noise canceller might be utilized to cancel its contribution. [11]

Masimo Signal Extraction Technology rejects the conventional wisdom and begins with an understanding that during patient motion the venous blood, being at a relatively low pressure, is quite susceptible to the local effects of perturbation during motion. Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion, representing a significant source of in-band noise within the frequency bandwidth of interest. In addition, the venous blood is a strong absorber of light. Hence, it can represent a significant contributor to the total optical density during motion episodes. Furthermore, the venous blood saturation is normally lower than the arterial blood saturation. This explains why saturation values tend to drop in conventional pulse oximeter systems during episodes of patient motion.

Because it is not bound by a conventional “red over infrared” ratio approach, the Masimo SET system substantially eliminates the problems of motion artefact, low peripheral perfusion and most low signal-to-noise situations. This greatly extends the utility of SpO₂ in high motion, low signal and noise intensive environments.

The detected physiologic signal is generally composed of both desired signal (S) and undesired signal (N) or noise portions. To remove the effects of the undesired signal, some knowledge of the noise characteristics, or equivalently its noise reference (N'), must be known.

The adaptive filter will adjust its filtering characteristics, so that the noise reference input is transformed into an estimate of the undesired signal portion (N) of the physiologic signal. A subtracted subsequently removes the undesired signal from the physiologic signal to yield an estimate of the desired signal portion (S). The combination comprising the adaptive filter and the subtracted is commonly called an adaptive noise canceller (ANC).

The basis of measurement is presented with formula [1].

\[
\frac{I_{rd}}{I_{ir}} = \frac{S_{rd} + N_{rd}}{S_{ir} + N_{ir}} = \text{Ratio}(r) = \Rightarrow \% \text{SpO}_2 \ [1]
\]

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Supplemental oxygen administration, although a necessary and often life saving therapy, has side effects that are of relevance in the premature infant population. This population has a high risk for respiratory, neurologic, and ophthalmic compromise. There fore, there is a need for gentler, yet effective, oxygenation support.

The emergent availability of improved technology for oxygenation, monitoring and computing has facilitated the development of automated modes of regulation of supplemental oxygen for the preterm infant. Although this technology has been only used experimentally, preliminary results suggest future impact on patient care and practice. This, however, remains to be tested.

Future research will determine the role of this strategy in improving pulmonary, ophthalmic, and neurological outcome in premature infants, as well as in determining the true impact on caregiver workload.

CLiO2 system is a leap forward in neonatal ventilation. It has many advantages we have shown in this paper and still it is very safe for patients. When compared to standard systems, with manual gas mixture adjustments, it shows how it is difficult to keep SpO2 inside limits with routine and how SpO2 is kept inside limits with automated CLiO2.

By using modern, cutting edge pulse oximetry and advanced anticipating algorithms, this system ensures highest possible care for neonates in need of ventilation.

This kind of respirator itself is state of the art ventilator that covers complete range of patients, and combined with CLiO2, it becomes powerful tool for clinicians that take care of our smalles population.

This technique for automatic FiO2 control can potentially help in obtaining an optimal balance between respiratory, ophthalmic and neurological outcome while facilitating the care of preterm infants.

REFERENCES

