Metabox: The system for oxygen delivery monitoring – design and implementation

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Abstract. *This paper presents design and implementation of the oxygen delivery measurement system for use in patients dependent on extracorporeal membrane oxygenation (ECMO) or mechanical ventilation. Invented system called Metabox works on principle of measuring of flow through ventilator/ECMO patient system and difference between oxygen concentration in inspired/incoming and exspired/outcoming air. Metabox consists of pneumatic, electronic, electric and mechanical subsystems which are controlled by Metabox software implemented in the NI LabVIEW. Information from mass flow sensors and paramagnetic oxygen sensor are processed and visualized in Metabox software.*

The whole system is fully functional, customizable and tested in laboratory environment. Metabox is prepared to adapt any further improvements in order to best suit to operators requirements and habits.

Keywords

Oxygen delivery, biomedical device, hardware design, metabolism measurement.

1. Introduction

Oxygen delivery (DO_2) to tissues is one of the most crucial prerequisites of life. Its interruption causes significant functional disruption already within seconds and irreversible changes after several minutes.

In critically ill, specifically in heart failure patients, oxygenation is one of the major parameters to be closely watched and controlled by physicians. DO_2 reflects several vital systems status, such as blood flow, respiration, blood composition [1]. Also, since there are virtually no O_2 stores within the body the changes in oxygenation are among the earliest markers capable to unveil serious disruptions in the body.

At present, tissue oxygenation is estimated noninvasively by means of NIRS tissue oximetry or invasively from intermittent blood sampling. These methods represent a gold standard in oximetry and reflect well local oxygenation. However, none of these parameters provide quantitative assessment of a total amount of oxygen delivered to tissues [2]. This in turn reflects the ability of the cardiorespiratory apparatus to provide O_2 to saturate expected body needs for oxygen.

The disadvantage of measuring CO_2 production is a time delay caused by CO_2 buffers in human body . Since O_2 has no relevant buffers in human body deficit of O_2 is a real-time characteristic. Therefore O_2 consumption is very robust, sensible and fast index of metabolism even in circumstances where many other characteristics are untrustworthy. Knowledge of the current metabolism can help to assess the overall state of the whole organism and opens opportunity to better interpret other measured data.

Cardiac Physiology Experimental Laboratory of Charles University (First Faculty of Medicine) and Na Homolce Hospital expressed the interest in O_2 delivery continuous monitoring. The lab specified the project for the development of a standalone system, that would allow platform-independent measurement in ventilated, critically ill subjects with either spontaneous or extracorporeal circulation.

2. Designing process

The aim of this study was to design and build the system for measuring the oxygen delivery in intensive care – the Metabox. Metabox system has it's own requirements specific for clinical use and it has to be made of sufficient components compatible with environment where Metabox is intended to be used.

2.1 Requirements

Medical doctors from the Laboratory stated following requirements for Metabox. A (semi) automatic system for real-time analysis and monitoring of oxygen delivery in mechanically ventilated patients requiring intensive care. System must be robust, able to be synchronised with current method of data collection and to store data in current database, must measure O_2 concentration with < 0.1% error, must have response time 20 s or less, must be compatible with extra-corporeal membrane oxygenation (ECMO) systems and should be compatible with a range of medical ventilators.

Technical solution which meets requirements above would be a system consisting of O_2 sensor, mass flow sensor, valves controlling gas input (exspired, inspired, calibration gas), dehumidifier, pump, pneumatic control system, data acquisition system and data analysis and visualization systems.

2.2 Finding solutions

There were many approaches and alternatives to make Metabox an efficient system satisfying all the requirements of the Laboratory. Crucial moments of the whole project were O_2 sensor and data acquisition which is strongly connected with programming language/software to be used.

In agreement with the Laboratory LabVIEW by National Instruments (NI) was chosen as the programming language for its previous implementation in target laboratory. That made data acquisition system to be some of the NI products, because of the ease of implementation together with LabVIEW. OxyStar-100, CWE is used as the O_2 sensor. The Laboratory staff members have made a pre-project survey and bought this paramagnetic sensor for its reliability, high accuracy and low flow request (40 ml/min).

2.3 Function description

To measure an O_2 delivery D_{O2} effectively we need to know fraction of O_2 in inspiration gas F_{iO2}, fraction of O_2 in exspiration gas F_{eO2} and air flow through the whole system Q. Fractions of O_2 are measured by OxyStar-100 and air flow is measured by mass flow meter.

With those information the difference of O_2 concentrations d_{O2} could be found as:

$$d_{O2} = F_{iO2} - F_{eO2} \tag{1}$$

Further the O_2 delivery DO_2 is defined as:

$$DO_2 = Q \cdot d_{O2} \tag{2}$$

Oxygen delivery D_{O2} is value indicated in standard conditions (0°C, 1 atm).

3. Realization

The realization process consisted of selection of the best fitting components, setting up the pneumatic and sensor system, manufacturing pneumatic connectors, programming appropriate software to control pneumatic system and represent sensor outputs, designing electronic circuit and printed circuit board (PCB) and solving some additional problems that occurred during the realization. For the whole system scheme see Fig. 1.

3.1 Oxygen sensor

The oxygen sensors used in metabolism measurement are paramagnetic, fuel cell, or zirconium oxide [3]. All these analysers are very precise, additionally our application requires the sensor to have small flow demand and full scale (0-100%) of O_2 concentration. In normal spontaneous breathing of air there is a normal concentration of oxygen (20.93%) in inspired gas and lower level of O_2 (about 15-17%) in exspired gas [4]. In our application there are oxygen enrichment methods used in mechanical ventilation therefore O_2 concentration can reach 100%. In extreme conditions during ECMO there is a possibility of reaching also a value of O_2 concentration close to 0%. Small flow demand is essential, because air samples are taken from inspiration branch right on ventilator outcome and if there is high outflow the ventilator alarms a leakage in patient breathing circuit.

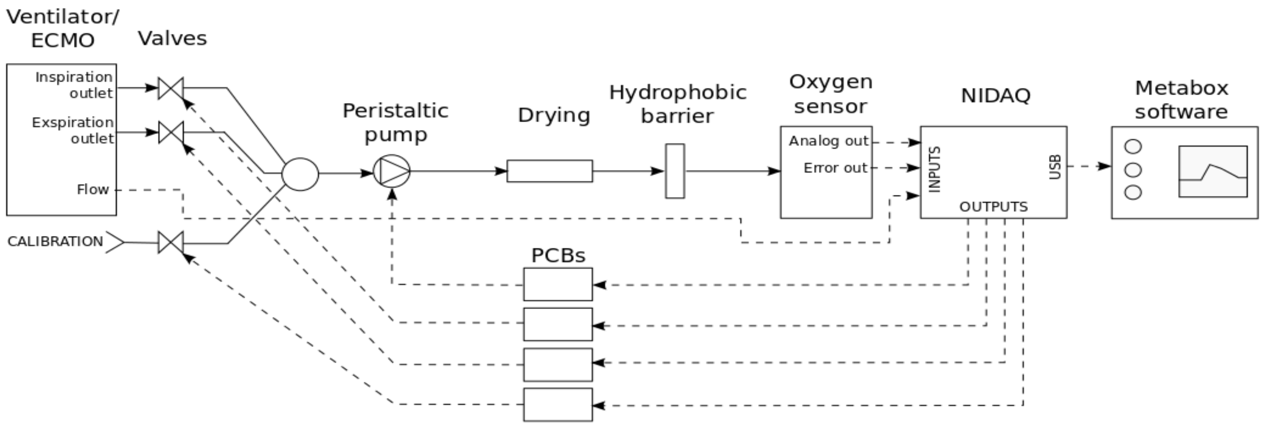

Fig. 1 Schematic of complete Metabox system with hardware parts, pneumatic connections (double lines) and signal routes (dashed)

Appropriate sensor proved to be OxyStar-100, CWE. OxyStar-100 is a paramagnetic oxygen sensor with accuracy ±0.1% O_2 and optimal sample flow 150–170 ml/min with amplified analog output. The examined gas has to be dry for OxyStar. That makes no problem in ECMO nor in inspiration gas because we take gas before humidification, but the relative humidity of exspired gas is mostly 100% at 37°C.

Metabox uses the insurance hydrophobic barrier polytetrafluoroethylene syringe filters (pore size 0.45 micrometers), Whatman. Filters are used to prevent accidental moisture entry to sensor. In case of moisture entrance the filter will block the flow. Blocked flow results in sensor error.

Exspired gas is dried using Nafion tube. Nafion tubing is six inches long tubing made of material selectively permeable for water vapour. Nafion tubing reduces humidity from 100% at 37°C to ambient humidity for flows lower than 50 ml/min and to 10% higher humidity than ambient for flows lower than 100 ml/min [5]. When this proofs to be insufficient during regular use, we are prepared to implement Peltier cooler to condensate water vapour although it would increase the death space volume therefore also transport delay.

If sensor comes to error state, it gives a zero concentration on output and lights up the light emitting diode (LED) on the front panel of the sensor. In order to transfer the error state information to LabVIEW, there is a need to implement a state machine consisting of photo-transistor covering the original LED and also an additional LED to preserve the hardware error state function.

3.2 Flow sensor

In accordance to make Metabox a reliable system we need to distinguish usage during mechanical ventilation and during ECMO. In case of mechanical ventilation recommended flow rate is 60 l/min in normal conditions and 100 l/min in obstructive airway disease patients [6]. On the other hand during ECMO constant flow up to 10 l/min is used. That results in usage of two independent flow sensors. Both sensors operate on the heat transfer principle to measure mass airflow. They consist of a microbridge Microelectronic and Microelectromechanical System (MEMS) where temperature-sensitive resistors are cooled by the flowing air. There is a need to analyse only dry air owing to the heat transfer technology. Dryness of analysed air is achieved by placement of sensor before humidifier in breathing circuit.

Flow sensor for mechanical ventilation is HAFUHH0100L4AXT, Honeywell with flow range 0–100 l/min, digital I^2C output. Flow sensor for mechanical ventilation is AWM5103VA, Honeywell with flow range 0–10 l, analog output.

3.3 Software

The software displaying outcomes and controlling the pneumatic system was programmed in LabView 2012, NI software [7]. LabView has been chosen because of its ongoing usage in laboratory and prior usage of this programming language experienced by some of target laboratory scientists. Scientist's knowledge of LabVIEW determine Metabox software to be customizable in case of need even after finishing Metabox project.

Pneumatic system control is performed by switching input valves and controlling the speed of peristaltic pump. Valves could be switched in defined time period with possibility to set the periodicity of calibration input. Peristaltic pump is driven by pulse width modulation signal (PWM) which could not be performed via the software because NI USB-6009 data acquisition device (NIDAQ) characteristics (listed bellow in Data acquisition and PCBs subsections). Therefore PWM is implemented in one of the PCBs and Metabox software via NIDAQ controls duty cycle ratio.

The signal from O_2 sensor is delayed due to death space of pneumatic system. Metabox software predicts delay on start from test loop observation and recommends it to the user. Than the O_2 concentration difference between inspired and exspired gas is counted from measured signal. Mean value of all inspiration samples after transient settling is subtracted from mean value of exspiration samples. This is repeated every sampling period.

The product of flow (mean value over the sampling period) and difference of O_2 concentration may be represented as consumed O_2 (more precise explanation in Function description subsection). The actual oxygen delivery is shown on software front panel numerically and also with the graphical progress history.

LabVIEW is multi-platform software tool with some restrictions. First intention was to make Metabox software compatible with Windows XP, Vista, 7 and Linux Mint or Ubuntu. During implementation the fact that Linux support is limited to Red Hat, Scientific and openSUSE distributions was discovered. Although it is possible to run LabVIEW software on Ubuntu based distributions, support for NI Data Acquisition tools is malfunctional but no function is guaranteed. NI LabVIEW should be supported on Windows XP, Vista, 7 but Metabox software was tested just on Windows XP. Testing on probably supported versions of Windows is going to be one of the further improvements of this project.

3.4 Data acquisition

For the purpose of data acquisition and control signals output device NI USB-6009 data acquisition device (NIDAQ) was chosen. NIDAQ is a bus-powered USB multifunction analog and digital input/output device with 8 analog inputs, 2 analog outputs and 12 digital I/O lines. NIDAQ in Metabox provides controlling signals to PCBs which controls pneumatic system. Controlling signals are three digital signals defining open state of valves, one analog signal controlling PWM duty cycle ratio via analog signal 0–5 V and constant 5V power line which provides power supply to PWM amplifiers.

The PWM has to be realized on PCB, because there is no hardware timer in NIDAQ. One of first experimental versions of Metabox software implemented PWM in LabVIEW and tried to run it on frequency on around 30 kHz. Because the information of wave switch is sent via USB in packet when the system has time to do so, the output signal is not even close to PWM.

3.5 PCBs

PCBs used in Metabox system enables 12V valves to be operated by NIDAQ with 5 V, 5 mA outputs and also provides optical isolation. Parts needed to be isolated are 5 V sensor and NIDAQ subsystem which has to be isolated from 12 V power subsystem.

Two types of PCBs are used. First one to control valve and second to generate PWM. Both are of the same template design with different mount. One template design makes the unassembled PCBs substitutable and makes easier maintenance. Differences between PCB assembled for PWM and PCB assembled for valve control are to be seen on Figure 2.

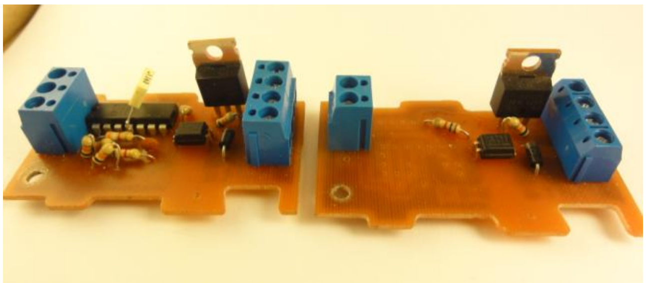

Fig. 2 Photo of PCBs. PCB assembled for PWM on the left and PCB assembled for optical and power isolation on the right.

3.6 Valves

There are industrial two-port solenoid valves VCA21-6G, SMC used in pneumatic system. VCA21 solenoids are designed for industrial use what makes them oversized in almost every characteristic. VCA21 solenoids are sufficient for prototyping but their dimension, consumption, connection type and heating makes them first part to be replaced in further versions of Metabox.

3.7 Pump

Unknown type of pump inside of the O_2 sensor which proved to be insufficient to suck the air through the whole pneumatic system made us to add a pump in the system. Peristaltic pump also provides a pressure barrier when Metabox is used in ECMO where ventilation gas pressure is high enough to damage the oxygen sensor.

Oxygen sensor is sensitive to gas flow therefore peristaltic pump is operated by PWM (12 V) to make around 10–20% higher gas flow than oxygen sensor pump. Near to the oxygen sensor there is an intentional leakage where unnecessary air is released.

3.8 Tubing (connectors)

Tubing was chosen with emphasis on rigidity (twist and inflate resistance) and minimal volume (minimises death space). After some tests 1.5 mm diameter has been proved to be sufficient.

Due to specific tubing use there were some special connectors to be manufactured. As a part of Metabox project those connectors and adapters has been made: tubing-luer, tubing-quarter inch, three tubing to one, tubing-pump connector (see Figure 3).

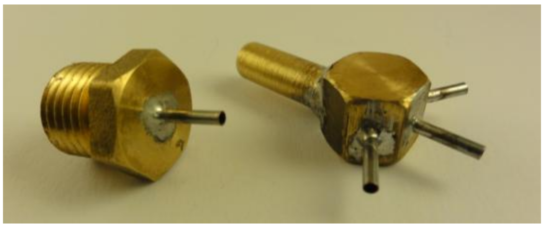

Fig. 3 Photo of connectors and reductions used in Metabox system

4. Conclusion and further improvements

The Metabox was designed and implemented with all the mechanical, electronic, electrical and pneumatic components as a fully functional oxygen delivery measurement system. The functionality was tested in laboratory conditions on experimental base. The Metabox system provides continuous oxygen delivery that enables advanced analysis through correlation with other biosignals. Further verification of accuracy, repeatability and reliability under various conditions will be held.

Metabox tests on pigs are planned and will be held in near future. All the data from pig experiments will be stored for further examination. It is expected that after animal experiments there will some problems arise, but high level of software customizability and hardware open design should help to solve problems quickly.

One of the possible problems expected is humidity in pneumatic system. We are already prepared to dry the air by addition of active drying subsystem (Peltier element) in front of sensor

Some of the long term improvements could be moving to a stand-alone system or moving software to Control web programming language and use this platform for online parameterisation of human breathing model in Modelica.

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