Medical Engineering and Physics 56 (2018) 36–41

Contents lists available at ScienceDirect

Medical Engineering and Physics

journal homepage: www.elsevier.com/locate/medengphy

Technical note

Development and characterization of a point-of care rate-based transcutaneous respiratory status monitor

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ARTICLE INFO

Article history:
Received 23 August 2017
Revised 15 March 2018
Accepted 25 March 2018

Keywords:
Noninvasive
Transcutaneous
Respiration
Blood gas
Sensor
Monitor

ABSTRACT

Blood gas measurements provide vital clinical information in critical care. The current "gold standard" for blood gas measurements involves obtaining blood samples, which can be painful and can lead to bleeding, thrombus formation, or infection. Mass transfer equilibrium-based transcutaneous blood gas monitors have been used since the 1970s, but they require heating the skin to ≥42 °C to speed up the transcutaneous gas diffusion. Thus, these devices have a potential risk for skin burns. Here we report a new generation of noninvasive device for respiratory status assessment. Instead of waiting for mass transfer equilibrium, the blood gas levels are monitored by measuring the transcutaneous diffusion rate, which is proportional to blood gas concentration. The startup time of this device is almost independent of skin temperature, so the measurement can be made at any body temperature. The test results show that this device can track the blood gas levels quickly even at normal body temperature.

1. Introduction

Partial pressures of arterial oxygen (paO_2) and carbon dioxide ($paCO_2$) are two of the most important respiratory parameters in intensive care. PaO_2 reflects the adequacy of oxygen delivery to the blood via lungs, and $paCO_2$ reflects the adequacy of ventilation to clear the metabolic byproducts from blood. Hypoxia is a condition in which the body or a region of the body is deprived of adequate oxygen supply. Severe hypoxia can cause multiple organ failure or even death. Hyperoxia occurs when tissues and organs are exposed to an excess supply of oxygen or higher than normal partial pressure of oxygen, and can lead to oxygen toxicity. During oxygen therapy for preterm neonates, the occurrence of hyperoxia increases the risk of retinopathy of prematurity [1–3]. Hypocapnia, a state of reduced carbon dioxide in the blood, may contribute to intraventricular hemorrhage, cerebral palsy, cognition developmental disorder, and auditory deficit whereas severe hypercapnia can cause intracranial hemorrhage, consciousness alterations, cataphora, and hyperspasmia [4–6].

Currently, arterial blood gas (ABG) measurement remains the gold standard for guiding respiratory management in intensive care units (ICU). Although reliable and accurate, it requires access to arterial blood by placing arterial line or repeated arterial punctures. Breaking the skin to collect blood samples is painful and can lead to bleeding, thrombus formation, or infection. For very small-size preterm neonates, the blood loss due to sampling sometimes even necessitates blood transfusions.

Transcutaneous blood gas monitor using electrochemical sensor has been introduced into ICU since its invention in the 1970s [7–9]. Although noninvasive, it needs to heat the skin to 42 °C or higher to accelerate the response, but still requires ~20 min for startup before any meaningful results can be provided. Due to the elevated temperature, skin burns can occur if the measurement lasts more than a few hours. Additionally, current devices drift and need to be recalibrated frequently. Capnography, the monitoring of CO_2 partial pressure in the respiratory gases, has been used as a monitoring tool during anesthesia and intensive care. Its disadvantages include frequent inaccuracy and low reliability in patients with chronic obstructive pulmonary disease. Since the 1980s, pulse oximetry has been used to measure the proportion of hemoglobin in arterial blood that is bound to oxygen [10,11]. Pulse oximetry is easy to use, and does not require heating the skin or calibration. However, its detection mechanism limits its usefulness only for the detection of hypoxia.

Given the disadvantages and limitations of current technologies, there is a need for the development of a new generation of noninvasive monitoring devices for fast assessment of respiratory

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https://doi.org/10.1016/j.medengphy.2018.03.009
1350-4533/

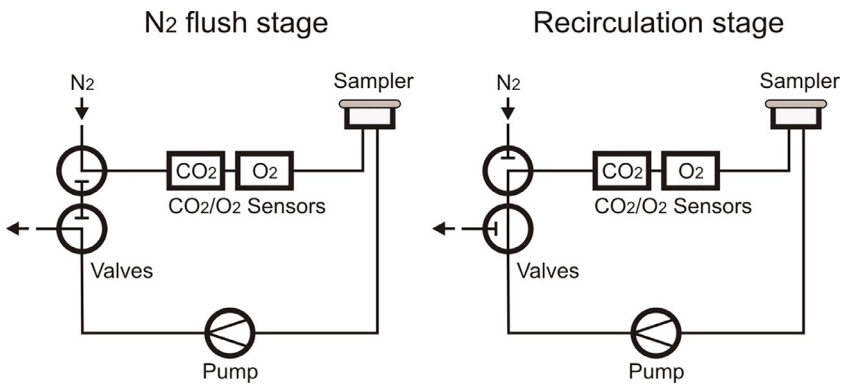

Fig. 1. Measurement principle and system design. Left: N_2 flush stage; Right: Recirculation stage.

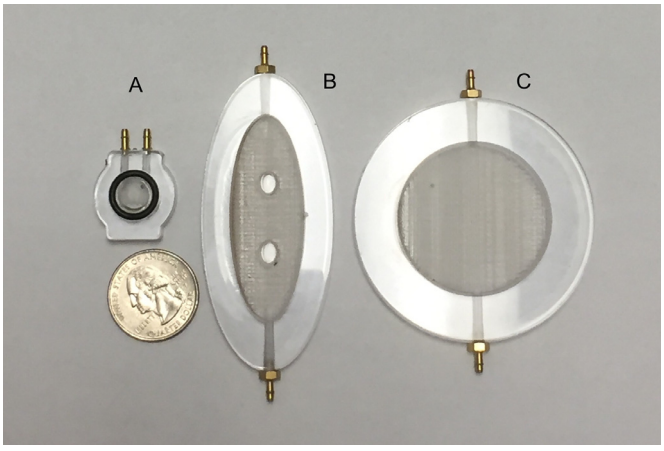

Fig. 2. Samplers used to collect the blood gases diffusing out of the skin.

status to better guide clinical practice [12]. Our goal is to develop a noninvasive respiratory status monitor that is safer and faster than current sensors.

2. Materials and methods

2.1. Principle of measurement

The principle of the noninvasive blood gas measurement is shown in Fig. 1. The system consists of a sampler, a gas pump, CO_2 and O_2 sensors, and two 3-way valves, which are connected by gas-impermeable tubing. To make a measurement, the sampler is placed on the skin and held in place with medical grade adhesive to prevent leaking. N_2 is then introduced into the system to flush out the ambient air (N_2 flush stage). After that, the 3-way valves are switched to allow the gases to recirculate between the sampler and the sensors (recirculation stage). During the recirculation stage, the N_2 atmosphere in the system serves as a sink to provide a concentration gradient for O_2 and CO_2 to diffuse out of the skin. The O_2/CO_2 concentrations are recorded continuously and the rate of increase in CO_2/O_2 partial pressure is calculated.

2.2. Construction of prototype

The sampler used to collect the blood gases diffusing out of the skin is an acrylic cup-shaped structure with two hose barb fittings (Fig. 2). Three different samplers were made, which have a sampling area of 0.9 cm^2, 8.5 cm^2 and 12.6 cm^2, respectively. The CO_2 sensor is a LI-820 CO_2 analyzer (LI-COR, Lincoln, Nebraska), which has a measurement range of 0–20,000 ppm with a 1-ppm resolution. The O_2 sensor is an oxy.IQ oxygen transmitter (GE Infrastructure Sensing, Billerica, MA), which measures oxygen in the range of 0–2,000 ppm with a resolution of 2 ppm. The sensors are designed to output their digitized values in serial format (RS 232). They are connected to a computer via serial-to-USB converter (i.e. FT232 from Future technology). The gas pump is a micro-diaphragm pump produced by Parker (Hollis, NH), which provides a flow rate up to 800 ml per minute. The 3-way valves are solenoid valves produced by the Lee Company (Westbrook, CT). They require only a very small power to operate, have small dimensions (<2″ in any direction), and are compatible with medical applications. The tubing that is used to connect the various components is tygon tubing produced by Saint Gobain (Malvern, PA), which has a very low CO_2/O_2 permeability. The electronics for activating the valves and digitizing the readings of the sensors are controlled by a dedicated microcontroller, which is also responsible for communicating the data to the computer. The program is written in LabVIEW, which controls the valves, reads the sensors, logs the data, and calculates the slopes in real time. All the time intervals are user adjustable so as to allow flexibility of the software.

2.3. Test of prototype

The prototype was extensively characterized in the lab after it was built. First, the double-sided medical grade adhesive tape produced by Adhesives Research (Glen Rock, PA) was cut into pieces in the same shape as the sampler. One piece of adhesive tape was applied to the opening of the sampler (Fig. 2). The measurement site on the body was wiped with an alcohol prep and let dry. Then, the sampler was attached to the skin by pressing the adhesive against it. In addition to using the adhesive, an elastic band was used for reinforcement, ensuring that the sampler stays well in case the skin is oily or rigorous movements are involved during measurement. The N_2 supply for purging the system was from a gas tank equipped with a pressure regulator, and the output pressure was set at ~0.5 PSI. Use of higher pressures can increase the N_2 flow rate, reduce the purging time, but can compromise the seal between the skin and the sampler, creating a leakage that will ultimately skew the results. The time intervals used in the tests were 30 s for N_2 flush and 60 s for recirculation. During the recirculation stage, the sensors were read every half a second and the slope was calculated by fitting the readings to a linear equation. The measurement cycle would repeat until it was stopped by pressing the stop button. After the test, the sampler was gently detached from the skin and the adhesive was peeled off the sampler.