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(54) **SYSTEMS AND METHODS FOR CONTROLLING A VENTILATOR**

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A62B 7/00 (2006.01)
F16K 31/02 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **128/204.23**; 600/323

(58) **Field of Classification Search**
USPC 128/200.24, 203.12, 203.14, 203.25, 128/204.18, 204.21, 204.23, 204.26; 600/300, 301, 310, 323, 333, 483, 484
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,315,990	A *	5/1994	Mondry	128/205.11
5,682,877	A *	11/1997	Mondry	128/204.23
5,682,898	A	11/1997	Aung et al.	
6,599,251	B2 *	7/2003	Chen et al.	600/485
6,702,752	B2	3/2004	Dekker	
6,760,608	B2	7/2004	Lynn	
6,848,444	B2	2/2005	Smith et al.	
6,930,608	B2	8/2005	Grajales et al.	
7,066,173	B2	6/2006	Banner et al.	
7,171,251	B2	1/2007	Sarussi et al.	
7,210,478	B2	5/2007	Banner et al.	
7,246,618	B2	7/2007	Habashi	
7,398,115	B2	7/2008	Lynn	
7,421,296	B1	9/2008	Benser et al.	
2001/0039951	A1 *	11/2001	Strickland, Jr.	128/204.22
2002/0072659	A1 *	6/2002	Claure et al.	600/323
2002/0112726	A1 *	8/2002	Schmidt et al.	128/204.23
2004/0059209	A1	3/2004	Al-Ali et al.	
2005/0109340	A1	5/2005	Tehrani	
2005/0247311	A1	11/2005	Vacchiano et al.	
2006/0237015	A1 *	10/2006	Berthon-Jones et al.	128/204.23
2006/0266355	A1 *	11/2006	Misholi	128/204.23

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0 996 358	5/2000
EP	1 790 283	5/2007

(Continued)

OTHER PUBLICATIONS

PCT International Search Report and the Written Opinion of the International Searching Authority, or the Declaration, Date of Mailing Oct. 29, 2010, Intl Application No. PCT/US2010/044950, Intl Filing Date: Aug. 10, 2010, Applicant: Nellcor Puritan Bennett LLC.

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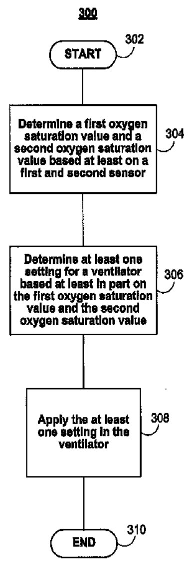
(57) **ABSTRACT**

A method and system for controlling a ventilator is disclosed. Oxygen saturation values from pulse oximeters may be used to adjust the settings of a ventilator. Multiple sensors and multiple oxygen saturation values in a fault tolerant pulse oximeter configuration may be used to provide a backup value or confidence measure, thereby increasing reliability and patient safety.

14 Claims, 5 Drawing Sheets



(56) References Cited

U.S. PATENT DOCUMENTS

2007/0000494	A1		1/2007	Banner et al.
2007/0123785	A1		5/2007	Lu et al.
2007/0149871	A1		6/2007	Sarussi et al.
2007/0293746	A1		12/2007	Sarussi et al.
2008/0014115	A1		1/2008	Johns
2008/0066752	A1		3/2008	Baker et al.
2008/0076988	A1		3/2008	Sarussi et al.
2008/0076990	A1		3/2008	Sarussi et al.
2008/0076992	A1		3/2008	Hete et al.
2008/0202525	A1		8/2008	Mitton et al.
2008/0236582	A1		10/2008	Tehrani
2008/0295839	A1		12/2008	Habashi
2008/0314385	A1		12/2008	Brunner et al.
2009/0241954	A1	*	10/2009	Karlsson 128/204.23

FOREIGN PATENT DOCUMENTS

JP	25034472		2/2005
JP	27167185		7/2007
WO	WO-86/00234	A1	1/1986
WO	WO-99/53834	A1	10/1999
WO	WO-00/16839	A1	3/2000
WO	WO-01/00264	A1	1/2001
WO	WO-01/00265	A1	1/2001
WO	02/47741	A2	6/2002

* cited by examiner

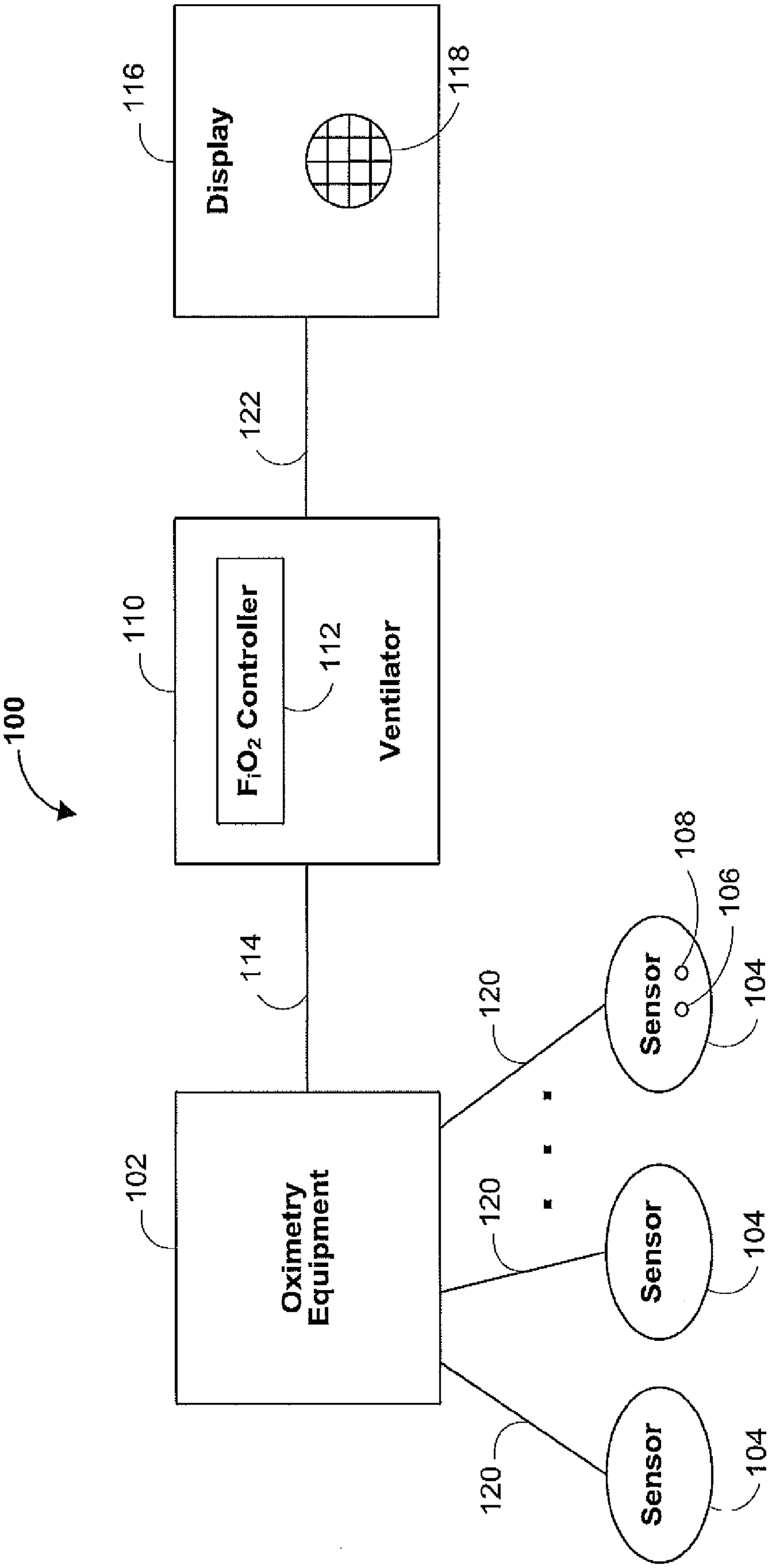

100
Display
116
118
122
F_iO_2 Controller
110
112
Ventilator
114
Oximetry Equipment
102
120
120
120
Sensor
Sensor
Sensor
104
104
104
106
108

FIG. 1

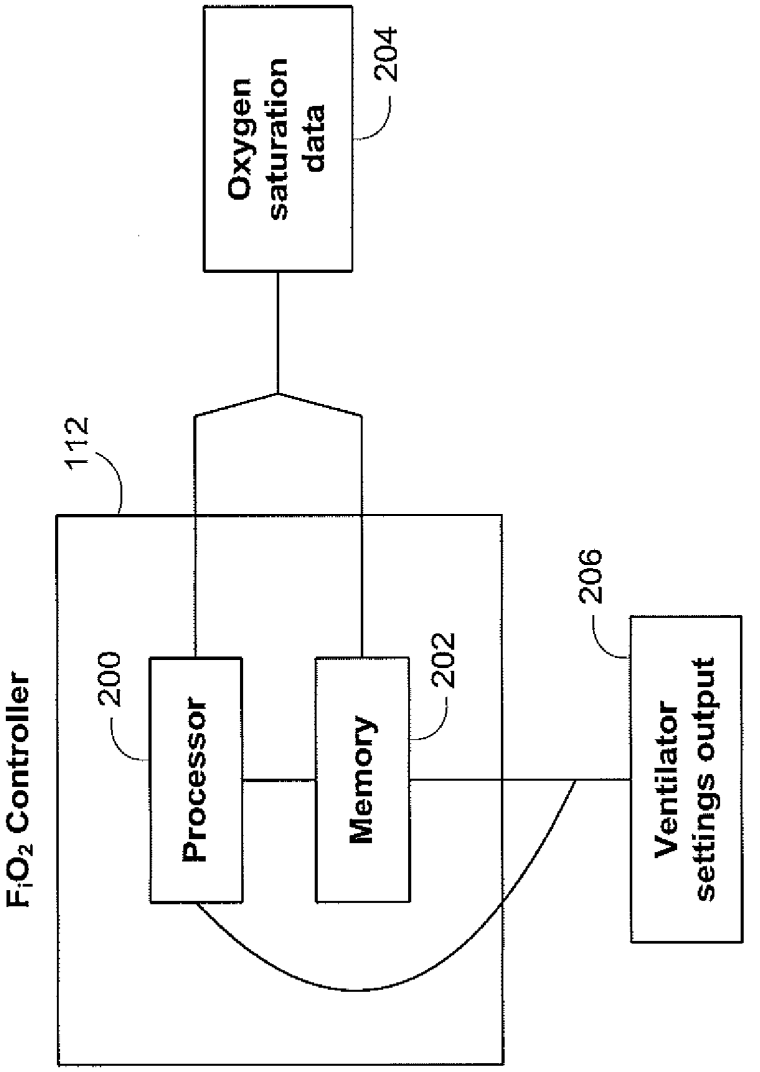

F_iO_2 Controller
112
200
Processor
202
Memory
204
Oxygen saturation data
206
Ventilator settings output

FIG. 2

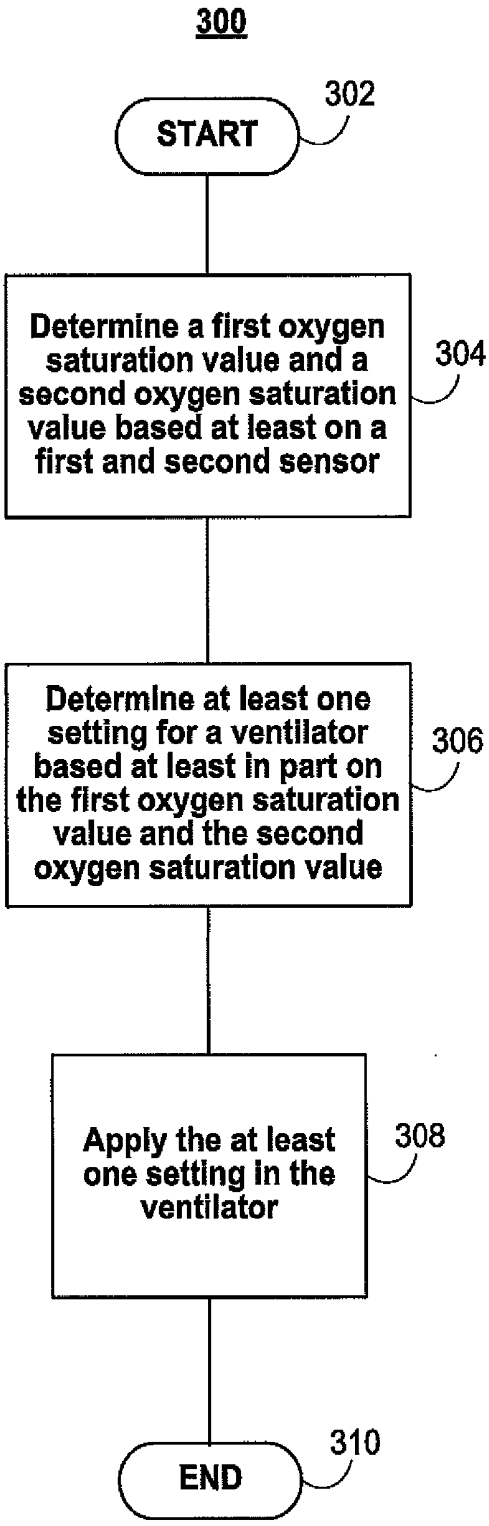

300
START
302
Determine a first oxygen saturation value and a second oxygen saturation value based at least on a first and second sensor
304
Determine at least one setting for a ventilator based at least in part on the first oxygen saturation value and the second oxygen saturation value
306
Apply the at least one setting in the ventilator
308
END
310

FIG. 3

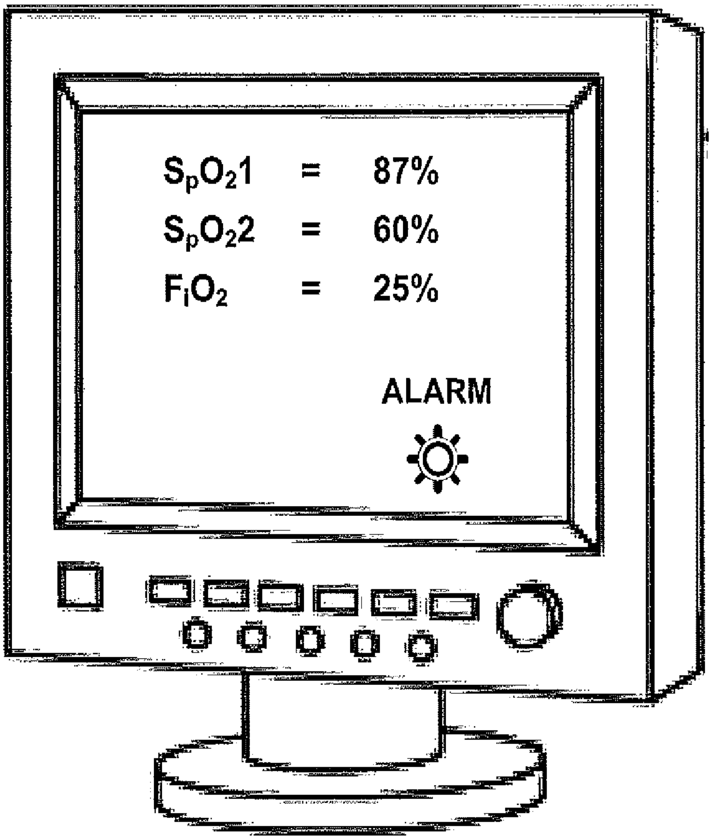


FIG. 4

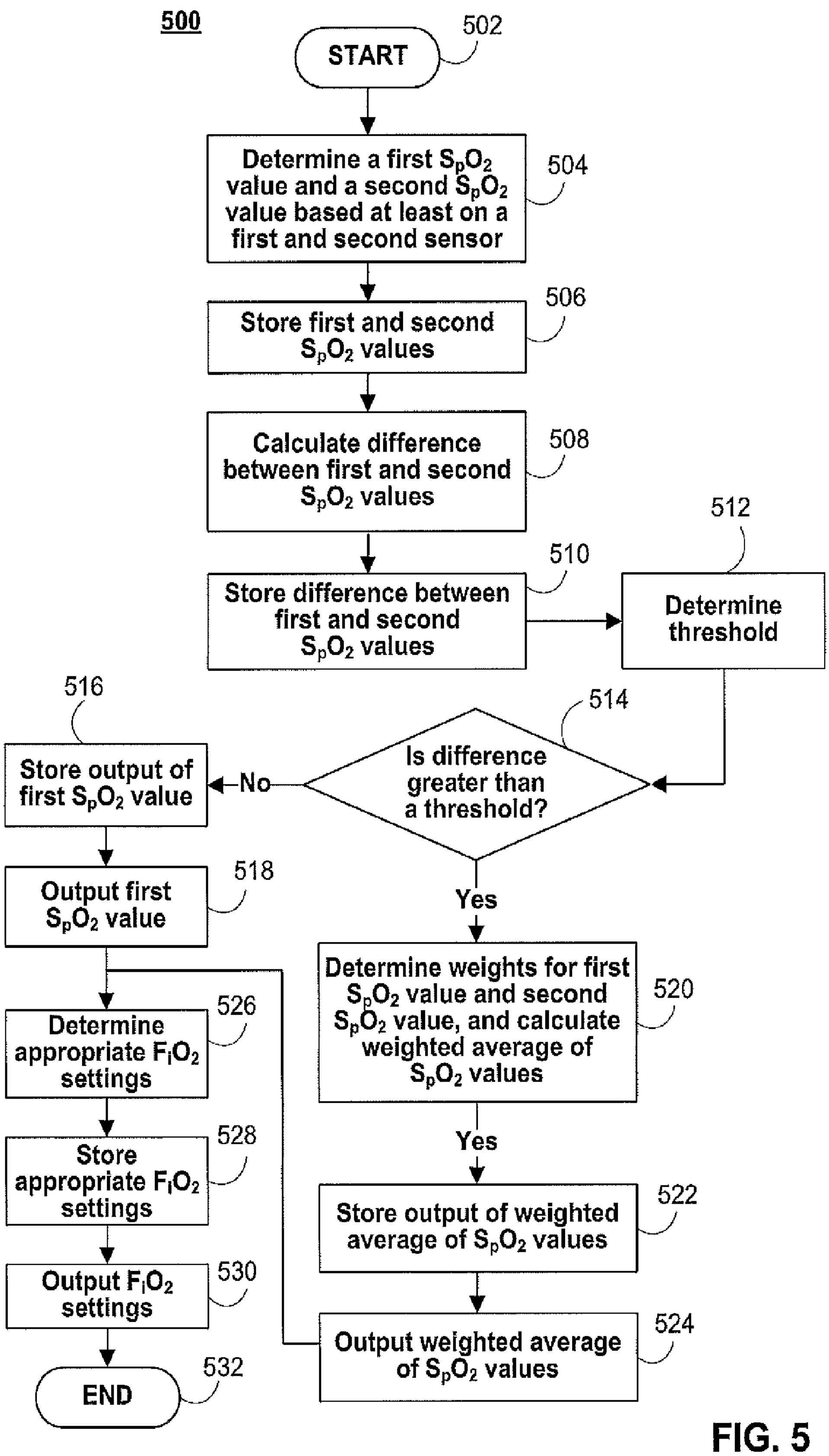

500
START
502
Determine a first S_pO_2 value and a second S_pO_2 value based at least on a first and second sensor
504
Store first and second S_pO_2 values
506
Calculate difference between first and second S_pO_2 values
508
Store difference between first and second S_pO_2 values
510
Determine threshold
512
Is difference greater than a threshold?
514
No
Store output of first S_pO_2 value
516
Output first S_pO_2 value
518
Yes
Determine weights for first S_pO_2 value and second S_pO_2 value, and calculate weighted average of S_pO_2 values
520
Yes
Store output of weighted average of S_pO_2 values
522
Output weighted average of S_pO_2 values
524
Determine appropriate F_iO_2 settings
526
Store appropriate F_iO_2 settings
528
Output F_iO_2 settings
530
END
532

FIG. 5

SYSTEMS AND METHODS FOR CONTROLLING A VENTILATOR

The present disclosure relates to a medical ventilator system and, more particularly, the present disclosure relates to a medical ventilator system the operation of which depends at least in part on a patient's medical state.

SUMMARY

In the present disclosure, a pulse oximetry system is integrated with a ventilator system. The purpose is to use the oxygen saturation (SpO_2) reading generated by the pulse oximetry system to adjust the inspired oxygen level (e.g., FiO_2) being delivered by the ventilator (e.g., by changing any one or more appropriate settings of the ventilator to effect the desired FiO_2). However, the quality of the measurement resulting from a received oxygen saturation signal can be degraded by, for example, noise or sensor malfunction. In a critical care environment, a more reliable oxygen saturation reading is desired to increase patient safety.

By using multiple SpO_2 values in a fault tolerant pulse oximeter configuration, the reliability of the SpO_2 values used to calculate the ventilator settings may be increased, thereby increasing patient safety. Multiple SpO_2 values (e.g., two or more values) may be obtained through the use of a respective number of sensors attached to the patient. The pulse oximeter sensors may be placed at different locations on the patient (e.g., one on the left foot, one on the right foot). For example, multiple SpO_2 readings from one or more pulse oximeters may be used to determine how well the multiple SpO_2 signals match based on a predetermined criteria or threshold.

For example, the criteria for determining the ventilator settings may include calculating a difference between the multiple SpO_2 readings and comparing the difference to a threshold. Alternatively or in addition, the criteria for determining the ventilator settings may include comparing one or more of the multiple SpO_2 values to a threshold. Alternatively or in addition, the criteria for determining the ventilator settings may include comparing the multiple SpO_2 values to respective historical SpO_2 readings. If the multiple SpO_2 values meet the criteria, then one SpO_2 value may be output to the ventilator for controlling FiO_2 or an average of two or more of the multiple SpO_2 values may be calculated and provided to the ventilator system in determining an appropriate FiO_2. If the multiple SpO_2 values do not meet the criteria, the system may hold until an adequate SpO_2 signal is detected, or an average SpO_2 value may be output to the ventilator for controlling FiO_2. The average of the multiple SpO_2 values may be a weighted average with predetermined or dynamic weights.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other features of the present disclosure, its nature and various advantages will be more apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings in which:

FIGS. **1** and **2** are block diagrams of illustrative ventilator systems in accordance with some embodiments;

FIG. **3** is a flow chart of illustrative steps involved in controlling a ventilator in accordance with an embodiment;

FIG. **4** shows an illustrative output device displaying ventilator settings and oxygen saturation values in accordance with an embodiment; and

FIG. **5** is a flow diagram of illustrative steps involved in controlling a ventilator in accordance with an embodiment.

DETAILED DESCRIPTION

Ventilators mechanically move breathable air into and out of the lungs of a patient, providing the mechanism of breathing for a patient who is physically unable to breathe, or breathing insufficiently. In the present disclosure, a pulse oximetry system is integrated with a ventilator system. The purpose is to use the oxygen saturation (SpO_2) reading generated by of the pulse oximetry system to adjust the inspired oxygen level (e.g., FiO_2) of being delivered by the ventilator (e.g., by changing any one or more appropriate settings of the ventilator to effect the desired FiO_2). However, the quality of the measurement resulting from a received oxygen saturation signal can be degraded by, for example, electromagnetic coupling from other electronic instruments, movement of the patient, sensor malfunction, and environmental factors that interfere with the connection between the patient and the monitoring device. In a critical care environment, a more reliable oxygen saturation reading is desired to increase patient safety. A single sensor may be unable to provide the reliable output required to safely and properly adjust the inspired oxygen level of a ventilator.

By using multiple SpO_2 values in a fault tolerant pulse oximeter configuration, the reliability of the SpO_2 values used to calculate the ventilator settings may be increased, thereby increasing patient safety. Multiple SpO_2 values (e.g., two or more values) may be obtained through the use of a respective number of sensors attached to the patient. Multiple SpO_2 values allow for increased reliability over a single SpO_2 value by providing a backup value or a confidence measure. The pulse oximeter sensors may be placed at different locations on the patient (e.g., one on the left foot, one on the right foot). For example, if a first SpO_2 value exhibits signs of high noise interference (e.g., low signal quality), another SpO_2 value with a more reliable reading may be used instead to calculate the proper setting for a ventilator. As an alternative or in addition to the above, multiple SpO_2 values may be averaged to ensure the proper calculation of the ventilator setting. Various methods of using multiple SpO_2 values to calculate ventilator settings are discussed in further detail below.

An oximeter is a medical device that may determine the oxygen saturation of the blood. One common type of oximeter is a pulse oximeter, which may indirectly measure the oxygen saturation of a patient's blood (as opposed to measuring oxygen saturation directly by analyzing a blood sample taken from the patient) and changes in blood volume in the skin. Ancillary to the blood oxygen saturation measurement, pulse oximeters may also be used to measure the pulse rate of the patient. Pulse oximeters typically measure and display various blood flow characteristics including, but not limited to, the oxygen saturation of hemoglobin in arterial blood.

An oximeter may include a light sensor that is placed at a site on a patient, typically a fingertip, toe, forehead or earlobe, or in the case of a neonate, across a foot. The oximeter may pass light using a light source through blood perfused tissue and photoelectrically sense the absorption of light in the tissue. For example, the oximeter may measure the intensity of light that is received at the light sensor as a function of time. A signal representing light intensity versus time or a mathematical manipulation of this signal (e.g., a scaled version thereof, a log taken thereof, a scaled version of a log taken thereof, etc.) may be referred to as the photoplethysmograph (PPG) signal. In addition, the term "PPG signal," as used herein, may also refer to an absorption signal (i.e., representing the amount of light absorbed by the tissue) or any suitable mathematical manipulation thereof. The light intensity or the amount of light absorbed may then be used to calculate the amount of the blood constituent (e.g., oxyhemoglobin) being measured as well as the pulse rate and when each individual pulse occurs.

The light passed through the tissue is selected to be of one or more wavelengths that are absorbed by the blood in an amount representative of the amount of the blood constituent present in the blood. The amount of light passed through the tissue varies in accordance with the changing amount of blood constituent in the tissue and the related light absorption. Red and infrared wavelengths may be used because it has been observed that highly oxygenated blood will absorb relatively less red light and more infrared light than blood with a lower oxygen saturation. By comparing the intensities of two wavelengths at different points in the pulse cycle, it is possible to estimate the blood oxygen saturation of hemoglobin in arterial blood.

When the measured blood parameter is the oxygen saturation of hemoglobin, a convenient starting point assumes a saturation calculation based on Lambert-Beer's law. The following notation will be used herein:

$$I(\lambda,t)=I_o(\lambda)\exp(-(s\beta_o(\lambda)+(1-s)\beta_r(\lambda))l(t)) \tag{1}$$

where:
λ=wavelength;
t=time;
I=intensity of light detected;
I_o=intensity of light transmitted;
s=oxygen saturation;
β_o, β_r=empirically derived absorption coefficients; and
l(t)=a combination of concentration and path length from emitter to detector as a function of time.

The traditional approach measures light absorption at two wavelengths (e.g., red and infrared (IR)), and then calculates saturation by solving for the "ratio of ratios" as follows.

1. First, the natural logarithm of (1) is taken ("log" will be used to represent the natural logarithm) for IR and Red

$$\log I=\log I_o-(s\beta_o+(1-s)\beta_r)l \tag{2}$$

2. (2) is then differentiated with respect to time

$$\frac{d\log I}{dt}=-(s\beta_0+(1-s)\beta_r)\frac{dl}{dt} \tag{3}$$

3. Red (3) is divided by IR (3)

$$\frac{d\log I(\lambda_R)/dt}{d\log I(\lambda_{IR})/dt}=\frac{s\beta_0(\lambda_R)+(1-s)\beta_r(\lambda_R)}{s\beta_0(\lambda_{IR})+(1-s)\beta_r(\lambda_{IR})} \tag{4}$$

4. Solving for s

$$s=\frac{\frac{d\log I(\lambda_{IR})}{dt}\beta_r(\lambda_R)-\frac{d\log I(\lambda_R)}{dt}\beta_r(\lambda_{IR})}{\frac{d\log I(\lambda_R)}{dt}(\beta_0(\lambda_{IR})-\beta_r(\lambda_{IR}))-\frac{d\log I(\lambda_{IR})}{dt}(\beta_0(\lambda_R)-\beta_r(\lambda_R))}$$

Note in discrete time

$$\frac{d\log I(\lambda,t)}{dt}\simeq\log I(\lambda,t_2)-\log I(\lambda,t_1)$$

Using log A−log B=log A/B,

$$\frac{d\log I(\lambda,t)}{dt}\simeq\log\left(\frac{I(t_2,\lambda)}{I(t_1,\lambda)}\right)$$

So, (4) can be rewritten as

$$\frac{\frac{d\log I(\lambda_R)}{dt}}{\frac{d\log I(\lambda_{IR})}{dt}}\simeq\frac{\log\left(\frac{I(t_1,\lambda_R)}{I(t_2,\lambda_R)}\right)}{\log\left(\frac{I(t_1,\lambda_{IR})}{I(t_2,\lambda_{IR})}\right)}=R \tag{5}$$

where R represents the "ratio of ratios." Solving (4) for s using (5) gives

$$s=\frac{\beta_r(\lambda_R)-R\beta_r(\lambda_{IR})}{R(\beta_0(\lambda_{IR})-\beta_r(\lambda_{IR}))-\beta_0(\lambda_R)+\beta_r(\lambda_R)}.$$

From (5), R can be calculated using two points (e.g., PPG maximum and minimum), or a family of points. One method using a family of points uses a modified version of (5). Using the relationship

$$\frac{d\log I}{dt}=\frac{dI/dt}{I} \tag{6}$$

now (5) becomes

$$\begin{aligned}\frac{\frac{d\log I(\lambda_R)}{dt}}{\frac{d\log I(\lambda_{IR})}{dt}}&\simeq\frac{\frac{I(t_2,\lambda_R)-I(t_1,\lambda_R)}{I(t_1,\lambda_R)}}{\frac{I(t_2,\lambda_{IR})-I(t_1,\lambda_{IR})}{I(t_1,\lambda_{IR})}}\\&=\frac{[I(t_2,\lambda_R)-I(t_1,\lambda_R)]I(t_1,\lambda_{IR})}{[I(t_2,\lambda_{IR})-I(t_1,\lambda_{IR})]I(t_1,\lambda_R)}\\&=R\end{aligned} \tag{7}$$

which defines a cluster of points whose slope of y versus x will give R where

$$x(t)=[I(t_2,\lambda_{IR})-(t_1,\lambda_{IR})]I(t_1,\lambda_R)$$

$$y(t)=[I(t_2,\lambda_R)-I(t_1,\lambda_R)]I(t_1,\lambda_{IR})$$

$$y(t)=Rx(t) \tag{8}$$

FIG. **1** is a perspective view of an embodiment of a ventilator system **100** in accordance with some embodiments. According to an embodiment, system **100** may include oximetry equipment **102** and a plurality of sensors forming a sensor array **104**. According to another embodiment, oximetry equipment **102** may include a plurality of pulse oximeters (not shown) with one or more sensors. Each of the plurality of pulse oximeters in oximetry equipment **102** may be communicatively coupled to the other pulse oximeters via cables (not shown). However, in other embodiments, a wireless transmission device (not shown) or the like may be used instead of or in addition to the cables.

Sensor **104** may include an emitter **106** for emitting light at two or more wavelengths into a patient's tissue. A detector **108** may also be provided in sensor **104** for detecting the light originally from the emitter **106** that emanates from the patient's tissue after passing through the tissue.

Each of the sensors **104** of the sensor array may be a complementary metal oxide semiconductor (CMOS) sensor. Alternatively, each sensor of the array may be charged coupled device (CCD) sensor. In another embodiment, the sensor array may be made up of a combination of CMOS and CCD sensors. The CCD sensor may comprise a photoactive region and a transmission region for receiving and transmitting data whereas the CMOS sensor may be made up of an integrated circuit having an array of pixel sensors. Each pixel may have a photodetector and an active amplifier.

According to an embodiment, emitter **106** and detector **108** may be on opposite sides of a digit such as a finger or toe, in which case the light that is emanating from the tissue has passed completely through the digit. In an embodiment, emitter **106** and detector **108** may be arranged so that light from emitter **106** penetrates the tissue and is reflected by the tissue into detector **108**, such as a sensor designed to obtain pulse oximetry data from a patient's forehead.

In an embodiment, the sensors may be connected to and draw its power from oximetry equipment **102**. In another embodiment, the sensors may be wirelessly connected to oximetry equipment **102** and include its own battery or similar power supply (not shown). Oximetry equipment **102** may be configured to calculate physiological parameters based at least in part on data received from sensors **104** relating to light emission and detection. In an alternative embodiment, the calculations may be performed on the monitoring device itself and the result of the oximetry reading may be passed to oximetry equipment **102**.

In an embodiment, system **100** may include a ventilator **110**. Ventilator **110** may be coupled to the patient via a nasal mask, a tracheotomy cannula, or any other suitable patient circuit for ventilation. Ventilator **110** may be powered by a battery (not shown) or by a conventional power source such as a wall outlet.

In an embodiment, system **100** may include an FiO_2 controller **104**. In an embodiment, FiO_2 controller **104** may be incorporated in the same housing as ventilator **110** as shown in FIG. **1**. Alternatively, FiO_2 controller **104** may be a part of oximetry equipment **102**, or FiO_2 controller **104** may be an external or stand-alone component of system **100**.

FiO_2 controller **104** may receive the patient's oxygen saturation data from oximetry equipment **102** to adjust the ventilation settings of ventilator **110**. In an embodiment, the ventilator settings may include the fraction of inspired oxygen (FiO_2), tidal volume, respiratory rate, peak inspiratory flow rate, positive end-expiratory pressure (PEEP), any other suitable ventilator setting, or any combination thereof. In an embodiment, the ventilator settings may be machine commands to adjust the ventilator based on the calculated FiO_2, tidal volume, respiratory rate, peak inspiratory flow rate, PEEP, any other suitable ventilator setting, or any combination thereof.

In an embodiment, FiO_2 controller **104** may output FiO_2 settings to ventilator **110** and ventilator **110** may calculate the appropriate ventilator settings, or FiO_2 controller **104** may calculate the appropriate ventilator settings and output the ventilator settings to ventilator **110**. It will be understood that the FiO_2 settings and/or ventilator settings may be calculated by FiO_2 controller **104**, oximetry equipment **102**, ventilator **110**, any suitable processing device, or any combination thereof.

In an embodiment, ventilator **110** may be communicatively coupled to oximetry equipment **102** via cables **114**. However, in other embodiments, a wireless transmission device (not shown) or the like may be used instead of or in addition to cables **114**.

In an embodiment, system **100** may include a display **116** configured to display the physiological parameters or other information about the system. The display may include a cathode ray tube display, a flat panel display such as a liquid crystal display (LCD) or a plasma display, or any other type of display now known or later developed. Display **116** may be configured to provide a display of information from oximetry equipment **102**, ventilator **110**, FiO_2 controller **104**, from other medical monitoring devices or systems (not shown) or any combination thereof. For example, display **116** may be configured to display an estimate of a patient's blood oxygen saturation generated by oximetry equipment **102** (referred to as an "SpO_2" measurement), pulse rate information from oximetry equipment **102**, blood pressure from a blood pressure monitor (not shown), and ventilator settings from ventilator **110**. In the embodiment shown, display **116** may also include a speaker **118** to provide an audible sound that may be used in various other embodiments, such as for example, sounding an audible alarm in the event that a patient's physiological parameters are not within a predefined normal range.

In an embodiment, sensors **104** may be communicatively coupled to oximetry equipment **102** via cables **120**. However, in other embodiments, a wireless transmission device (not shown) or the like may be used instead of or in addition to cables **120**.

Display **116** may be communicatively coupled to ventilator **110** via a cable **122** that is coupled to a sensor input port or a digital communications port, and/or may communicate wirelessly (not shown). Display **116** may be communicatively coupled to oximetry equipment **102** via a cable (not shown) that is coupled to a sensor input port or a digital communications port, and/or may communicate wirelessly. In addition, oximetry equipment **102**, ventilator **110**, and/or display **116** may be coupled to a network to enable the sharing of information with servers or other workstations (not shown). Display **116** may be powered by a battery (not shown) or by a conventional power source such as a wall outlet.

FIG. **2** is a block diagram of an FiO_2 controller, such as FiO_2 controller **112** of FIG. **1**, in accordance with an embodiment. In an embodiment, processor **200** may be adapted to execute software, which may include an operating system and one or more applications, as part of performing the functions described herein. The data in FiO_2 controller **112** may be stored in a memory such as memory **202**, which may be a read-only memory (ROM), a random access memory (RAM), or any suitable computer-readable media that may be used in the system for data storage. Computer-readable media are capable of storing information that can be interpreted by processor **200**. This information may be data or may take the form of computer-executable instructions, such as software applications, that cause the processor to perform certain functions and/or computer-implemented tasks. Depending on the embodiment, such computer-readable media may include computer storage media and communication media. Computer storage media may include volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage of information such as computer-readable instructions, data structures, program modules or other data. Computer storage media may include, but is not limited to, RAM, ROM, EPROM, EEPROM, flash memory or other solid state memory technology, CD-ROM, DVD, or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by components of the system.

In an embodiment, processor **200** may receive from oximetry equipment **102** the patient's physiological parameters, such as oxygen saturation data **202**, and calculate an output, such as ventilator settings output **206**. Processor **200** may execute various processes and/or make use of look-up tables based on the value of the received signals and/or data corresponding to oxygen saturation data **202**. In an embodiment, the real-time and historical oxygen saturation data **204** and the calculations of processor **200** may be stored in memory **202**.

In an embodiment, oxygen saturation data **202** may contain information about sensor **104**, such as what type of sensor it is (e.g., whether the sensor is intended for placement on a forehead or digit). Oxygen saturation data **202** may contain information specific to the patient, such as, for example, the patient's age, weight, and diagnosis. The information which may be included in oxygen saturation data **202** may allow processor **200** to determine ventilator settings output **206**, as well as, for example, patient-specific threshold ranges in which the patient's physiological parameter measurements should fall and to enable or disable the determination of additional physiological parameters.

Oxygen saturation data **202** may include signal quality information. For example, low signal quality measurements may indicate that a patient is moving or that a sensor has malfunctioned, in which case measurements may be delayed or alternate sensor values may be used until a higher quality measurement can be obtained. Signal quality information may come from an electromagnetic noise measuring device (not shown) or a signal arising from sensor **104** indicating a malfunction or undesirable operating condition. In an embodiment, a visual display to indicate low signal quality may be shown on display **116**, a audible alarm may be generated via speaker **118**, any suitable alert may be generated, or any combination thereof. The signal quality information which may be included in oxygen saturation data **202** may allow processor **200** to determine ventilator settings output **206**.

In an embodiment, ventilator settings output **206** may be retrieved from memory **202** and/or processor **200**, and may be communicated to ventilator **110**. In an embodiment, ventilator settings output **206** may contain an appropriate FiO_2 value for the patient and/or machine commands to ventilator **110** based on a calculated appropriate FiO_2 value.

FIG. **3** is a flow chart of illustrative steps involved in controlling a ventilator in accordance with some embodiments. Process **300** may begin at step **302**. In an embodiment, at step **304**, two or more oxygen saturation values (e.g., SpO_2 values) may be taken at about the same time based on respective signals (e.g., PPG signals) from two or more different sensors **104** coupled to one or more pulse oximeters in oximetry equipment **102**, the sensors being attached to a patient (FIG. **1**). It will be understood that, in some embodiments, a single pulse oximeter may be used having multiple channels each of which receives a respective sensor signal from the two or more sensors **104**. In some embodiments, a single sensor may be used, the signal from which may be provided to two or more pulse oximeter devices (e.g., that are different models or use different SpO_2 calculation techniques) in order to provide the two or more respective SpO_2 values. For purposes of brevity and clarity, and not by way of limitation, the present disclosure shall refer to embodiments in which multiple sensors are used.

Multiple SpO_2 values allow for increased reliability over a single SpO_2 value by providing, for example, a backup value or a confidence measure. Each oxygen saturation value may be calculated using one or more signals that may be obtained from one or more sensors **104** or pulse oximeters in oximetry equipment **102**. For purposes of brevity and clarity, and not by way of limitation, the signals from sensors **104** are described in the context of being PPG signals. In an embodiment, a PPG signal may be obtained from the patient using one or more sensors **104** in real time. In an embodiment, the PPG signal may have been stored in oximetry equipment **102** in the past and may be accessed by oximetry equipment **102** to be processed.

In an embodiment, at step **306**, at least one setting for a ventilator may be determined based at least in part on the first and second oxygen saturation values. In an embodiment, the ventilator setting may be the fraction of inspired oxygen (FiO_2), tidal volume, respiratory rate, peak inspiratory flow rate, positive end-expiratory pressure (PEEP), any other suitable ventilator setting, or any combination thereof. In an embodiment, the ventilator setting may be machine commands to adjust the ventilator based on the calculated FiO_2, tidal volume, respiratory rate, peak inspiratory flow rate, PEEP, any other suitable ventilator setting, or any combination thereof.

In an embodiment, the ventilator setting may be determined by calculating a difference between two oxygen saturation values taken at about the same time based on respective PPG signals from two different sensors. For example, if the difference between the two oxygen saturation values is less than a threshold, the first oxygen saturation value may be used as the oxygen saturation metric (i.e., the oxygen saturation value used to calculate the ventilator setting). The threshold may be predetermined, dynamically calculated, inputted by a physician, or any combination thereof. If the difference is greater than a threshold, the first oxygen saturation value may be used as a default oxygen saturation metric. In the alternative, if the difference between the two oxygen saturation values is greater than a threshold, an average of the first and second saturation values may be used as the oxygen saturation metric used to calculate at least one ventilator setting. Alternatively, if the difference between the two oxygen saturation values is greater than a threshold, a historical oxygen saturation metric that was acceptable (e.g., where the difference between the oxygen saturation values was less than a threshold) may be used to calculate at least one ventilator setting. For purposes of brevity and clarity, and not by way of limitation, the calculations are performed in the context of two sensors and two oxygen saturation values. However, it will be understood that more than two sensors or oxygen saturation values may be used to determine the oxygen saturation metric.

In an embodiment, the ventilator setting may be determined by comparing to a threshold at least one of the two oxygen saturation values taken at about the same time based on respective PPG signals from two different sensors. The threshold may be predetermined, dynamically generated, inputted by a physician, or any combination thereof. For example, if both the first and second oxygen saturation values are less than a threshold, then the first oxygen saturation value may be used as the oxygen saturation metric used to calculate the appropriate ventilator setting. If only one of the oxygen saturation values is less than a threshold, then the oxygen saturation value that is less than the threshold may be used as the oxygen saturation metric used to calculate the appropriate ventilator setting. If both the first and second oxygen saturation values are greater than a threshold, the first oxygen saturation value may be used as a default oxygen saturation metric. In the alternative, if both the first and second oxygen saturation values are greater than a threshold, an average of the first and second saturation values may be used as the oxygen saturation metric used to calculate at least one ventilator setting. Alternatively, if both the first and second oxygen saturation values are greater than a threshold, a historical oxygen saturation metric that was acceptable (e.g., both oxygen saturation values were less than a threshold) may be used to calculate at least one ventilator setting. For purposes of brevity and clarity, and not by way of limitation, the calculations are performed in the context of two sensors and two oxygen saturation values. However, more than two sensors or oxygen saturation values may be used to determine the oxygen saturation metric.

In an embodiment, the ventilator setting may be determined by taking two oxygen saturation values taken at about the same time based on respective PPG signals from two different sensors and analyzing the change or trend of the oxygen saturation values in time. For example, a first change in the oxygen saturation value may be calculated by taking the difference between the first oxygen saturation value and a respective first previous oxygen saturation value, a second change in the oxygen saturation value may be calculated by taking the difference between the second oxygen saturation value and a respective second previous oxygen saturation value. In an embodiment, at least one of the first and second changes in oxygen saturation may be compared to a threshold. The threshold may be predetermined, dynamically generated, inputted by a physician, or any combination thereof. If the first and second changes in oxygen saturation are less than a threshold, then the first oxygen saturation value may be used as the oxygen saturation metric used to calculate the appropriate ventilator setting. If only one change in oxygen saturation is less than a threshold, then the oxygen saturation value with the change less than the threshold may be used as the oxygen saturation metric used to calculate the appropriate ventilator setting. If both the first and second changes in oxygen saturation value are greater than a threshold, the first oxygen saturation value may be used as a default oxygen saturation metric. In the alternative, if both the first and second changes in oxygen saturation value are greater than a threshold, an average of the first and second saturation values may be used as the oxygen saturation metric used to calculate at least one ventilator setting. Alternatively, if both the first and second changes in oxygen saturation value are greater than a threshold, a historical oxygen saturation metric that was acceptable (e.g., both oxygen saturation changes were less than a threshold) may be used to calculate at least one ventilator setting. For purposes of brevity and clarity, and not by way of limitation, the calculations are performed in the context of two sensors and two oxygen saturation values. However, more than two sensors or oxygen saturation values may be used to determine the oxygen saturation metric.

In an embodiment, an average of the oxygen saturation values may be used to determine an oxygen saturation metric suitable for calculating the ventilator setting. In an embodiment, the average may be a weighted average of the oxygen saturation values. The weights may be predetermined, dynamically generated, inputted by a physician, or any combination thereof. For example, the weights associated with each oxygen saturation value may be based on the signal quality information associated with each sensor—a higher weight may be associated with the oxygen saturation value with the better signal quality. Signal quality information may come from an electromagnetic noise measuring device or a signal arising from the sensor indicating a malfunction or undesirable operating condition.

It will be understood that averages, thresholds, any other suitable metric, or any combination thereof may be used to select or calculate an oxygen saturation metric for determining a ventilator setting.

Once the oxygen saturation metric is calculated, a ventilator setting may be determined using the oxygen saturation metric. For example, ventilatory support may be increased when the oxygen saturation metric indicates low oxygen saturation levels. Conversely, ventilatory support may be decreased as oxygen saturation levels increase, thus limiting the time at higher ventilation settings. In an embodiment, the ventilator setting may be the fraction of inspired oxygen (FiO_2), tidal volume, respiratory rate, peak inspiratory flow rate, positive end-expiratory pressure (PEEP), any other suitable ventilator setting, or any combination thereof. In an embodiment, the ventilator setting may be machine commands to adjust the ventilator based on the calculated FiO_2, tidal volume, respiratory rate, peak inspiratory flow rate, PEEP, any other suitable ventilator setting, or any combination thereof.

In an embodiment, at step **308**, the ventilator setting calculated in step **306** may be outputted to the ventilator, such as ventilator **110** in FIG. **1**. Ventilator **110** may accordingly adjust the oxygen delivered to a patient based on the ventilator setting determined above. Ventilator **110** may take the machine commands generated in step **306** above and adjust the mixture of air and oxygen flow to apply the calculated setting. In an embodiment, ventilator **110** may take the ventilator setting (e.g., the FiO_2 setting) and generate machine commands (e.g., via an FiO_2 controller such as FiO_2 controller **112** in FIG. **1**) to adjust the mixture of air and oxygen flow to apply the calculated ventilator setting. Following the applying of the ventilator setting in step **308**, process **300** may advance to step **310** and end.

In an embodiment, the ventilator settings, the oxygen saturation values, any other parameter, or any combination thereof may be outputted to display **116** (FIG. **1**) or any other display device communicatively coupled to system **100**. For example, the oxygen saturation values may be displayed on a display as illustrated by FIG. **4**. It will be understand that any other metric may be displayed to indicate the ventilator settings, oxygen saturation values, such as a status bar, a visual alarm, an audible alarm, any other suitable indication, or any combination thereof. For example, an audible and visual alarm may occur if the changes in oxygen saturation values are greater than a threshold as described above. The ventilator settings and oxygen saturation values may also be outputted to any other suitable output device, such as a computer, a computer-readable medium, a printer, any other suitable output device, or any combination thereof.

By way of illustration, FIG. **5** is a flow diagram of illustrative steps involved in controlling a ventilator in accordance with some embodiments. Process **500** may begin at step **502**. In an embodiment, at step **504**, oxygen saturation values (e.g., SpO_2 values) may be calculated using the signals (e.g., PPG signals) that may be obtained from sensors **104** that may be coupled to patient (FIG. **1**). In an embodiment, the PPG signal may be obtained from the patient using sensors **104** in real time. In an embodiment, the PPG signal may have been stored in oximetry equipment **102** in the past and may be accessed by oximetry equipment **102** to be processed.

After receiving the signal at step **504**, the first and second oxygen saturation values may be stored in processor **200** and/or memory **202** of FiO_2 controller **112** in step **506**. At step **508**, a difference between the first and second oxygen saturation values may be calculated. This difference may be stored in processor **200** and/or memory **202** of FiO_2 controller **112** in step **510**.

In an embodiment, at step **512**, a threshold may be determined. For example, a threshold may be input by a physician, retrieved from processor **200** or memory **202**, or dynamically generated based on patient data. At step **514**, the difference calculated in step **508** is compared to the threshold determined in step **512**. If the difference is not greater than the threshold, process **500** moves to step **516**, where the first oxygen saturation value may be stored in processor **200** and/or memory **202**. At step **518**, the first oxygen saturation value stored in step **516** may be output to ventilator **110**.

If the difference is greater than the threshold in step **514**, process **500** moves to step **520**. At step **520**, weights may be determined for each of the first and second oxygen saturation values determined in step **504**. For example, the signal quality information of sensors **104** may be used, increasing the weight of the oxygen saturation value with better signal quality. After determining the weights, a weighted average of the first and second oxygen saturation values is calculated. At step **522**, the weighted average of the oxygen saturation values is stored in processor **200** and/or memory **202**. At step **524**, the weighted average of the oxygen saturation values stored in step **522** may be output to ventilator **110**.

At step **526**, the output oxygen saturation metric of step **518** or step **524** may be used to determine an appropriate FiO_2 setting for the ventilator. This calculation may be performed by ventilator **110** or FiO_2 controller **112**. The calculations performed by ventilator **110** or FiO_2 controller **112** may be designed to adjust the FiO_2 levels, within limits, to respond to patient needs. For example, ventilator **110** or FiO_2 controller **112** may increase FiO_2 support when the patient develops low oxygen saturation. Conversely, the FiO_2 controller **112** may decrease FiO_2 support as the patient improves, thus limiting the time at higher FiO_2 settings. The appropriate FiO_2 levels may be calculated, for example, based at least in part on the following equations:

$$FiO2_i = FiO2_{i\text{-}1} + G_{err} * (\mathrm{Sat}_{target} - \mathrm{Sat}_i) + G_{der} * (\mathrm{Sat}_{i\text{-}1} - \mathrm{Sat}_i)$$

$$FiO2_i = \min(1.0, FiO2_i)$$

$$FiO2_i = \max(0.21, FiO2_i)$$

$$G_{err} = 0.25$$

$$G_{der} = 0.01$$

where:

$FiO2_i$=current FiO_2 setting;
$FiO2_{i\text{-}1}$=previous FiO_2 setting;
Sat_{target}=target SpO_2 value;
Sat_i=current SpO_2 value; and
$\mathrm{Sat}_{i\text{-}1}$=previous SpO_2 value.

The FiO_2 setting may be stored in processor **200** and/or memory **202** in step **528**. The calculated FiO_2 setting may be output to ventilator **110** in step **530**, and ventilator **110** may adjust the amount of oxygen delivered to the patient. Following the output of the FiO_2 setting, process **500** may advance to step **532** and end. In practice, one of more of the steps shown in processes **700** may be combined with other steps, performed in any suitable order, performed in parallel (e.g., simultaneously or substantially simultaneously), or removed.

The foregoing is merely illustrative of the principles of this disclosure and various modifications can be made by those skilled in the art without departing from the scope and spirit of the disclosure.

What is claimed is:

1. A method for controlling a ventilator in communication with a patient, the method comprising:

calculating a first oxygen saturation value based at least in part on a first signal generated by a first sensor attached to the patient;

calculating a second oxygen saturation value based at least in part on a second signal generated by a second sensor attached to the patient;

determining with processing equipment at least one setting for the ventilator based at least in part on the first oxygen saturation value and the second oxygen saturation value, wherein the determined at least one setting comprises a fractional inspired oxygen setting of the ventilator; and

applying the at least one setting.

2. The method of claim **1**, wherein the determining comprises calculating a difference between the first oxygen saturation value and the second oxygen saturation value.

3. The method of claim **1**, wherein the determining comprises determining whether at least one of the first oxygen saturation value and the second oxygen saturation value is greater than a threshold.

4. The method of claim **1**, wherein the determining comprises:

calculating a first change in the oxygen saturation of the patient by taking the difference between the first oxygen saturation value and a respective first previous oxygen saturation value;

calculating a second change in the oxygen saturation of the patient by taking the difference between the second oxygen saturation value and a respective second previous oxygen saturation value; and

determining whether at least one of the first change and the second change is greater than a threshold.

5. The method of claim **1**, wherein the determining comprises calculating an average of the first oxygen saturation value and the second oxygen saturation value.

6. The method of claim **5**, wherein the average is a weighted average and wherein the first oxygen saturation value and the second oxygen saturation value are associated with predetermined respective weights.

7. The method of claim **5**, wherein the average is a weighted average and wherein the first oxygen saturation value and the second oxygen saturation value are associated with dynamic respective weights.

8. The method of claim **1**, wherein applying the setting comprises modifying the fractional inspired oxygen setting of the ventilator.

9. A non-transitory computer-readable medium for controlling a ventilator, the non-transitory computer-readable medium having computer program instructions recorded thereon for:

calculating a first oxygen saturation value based at least in part on a first signal generated by a first sensor attached to a patient;

calculating a second oxygen saturation value based at least in part on a second signal generated by a second sensor attached to the patient;

determining with processing equipment at least one setting for the ventilator based at least in part on the first oxygen saturation value and the second oxygen saturation value, wherein the determined at least one setting comprises a fractional inspired oxygen setting of the ventilator; and

applying the at least one setting.

10. The non-transitory computer-readable medium of claim **9**, wherein the determining comprises calculating a difference between the first oxygen saturation value and the second oxygen saturation value.

11. The non-transitory computer-readable medium of claim **9**, wherein the determining comprises determining whether at least one of the first oxygen saturation value and the second oxygen saturation value is greater than a threshold.

12. The non-transitory computer-readable medium of claim **9**, wherein the determining comprises:

calculating a first change in the oxygen saturation of the patient by taking the difference between the first oxygen saturation value and a respective first previous oxygen saturation value;

calculating a second change in the oxygen saturation of the patient by taking the difference between the second oxygen saturation value and a respective second previous oxygen saturation value; and

determining whether at least one of the first change and the second change is greater than a threshold.

13. The non-transitory computer-readable medium of claim **9**, wherein the determining comprises calculating an average of the first oxygen saturation value and the second oxygen saturation value.

14. The non-transitory computer-readable medium of claim **9**, wherein applying the setting comprises modifying the fractional inspired oxygen setting of the ventilator.

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[标]申请(专利权)人(译)	内尔科尔普里坦贝内特公司		
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摘要(译)

公开了一种用于控制呼吸机的方法和系统。来自脉搏血氧计的氧饱和度值可用于调节呼吸机的设置。可以使用容错脉冲血氧计配置中的多个传感器和多个氧饱和度值来提供备用值或置信度测量，从而提高可靠性和患者安全性。