US 20170347917A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2017/0347917 A1

Falk et al.

(43) Pub. Date: Dec. 7, 2017

(54) NEWBORN RESPIRATION MONITORING SYSTEM AND METHOD

(71) Applicant: **General Electric Company**, Schenectady, NY (US)

(72) Inventors: **Steven Mitchell Falk**, Baltimore, MD (US); **Karen P. Starr**, Monkton, MD (US); **Sri Ramaprasad Prasad**, Ellicott City, MD (US)

(73) Assignee: **General Electric Company**, Schenectady, NY (US)

(21) Appl. No.: **15/174,158**

(22) Filed: **Jun. 6, 2016**

Publication Classification

(51) **Int. Cl.**

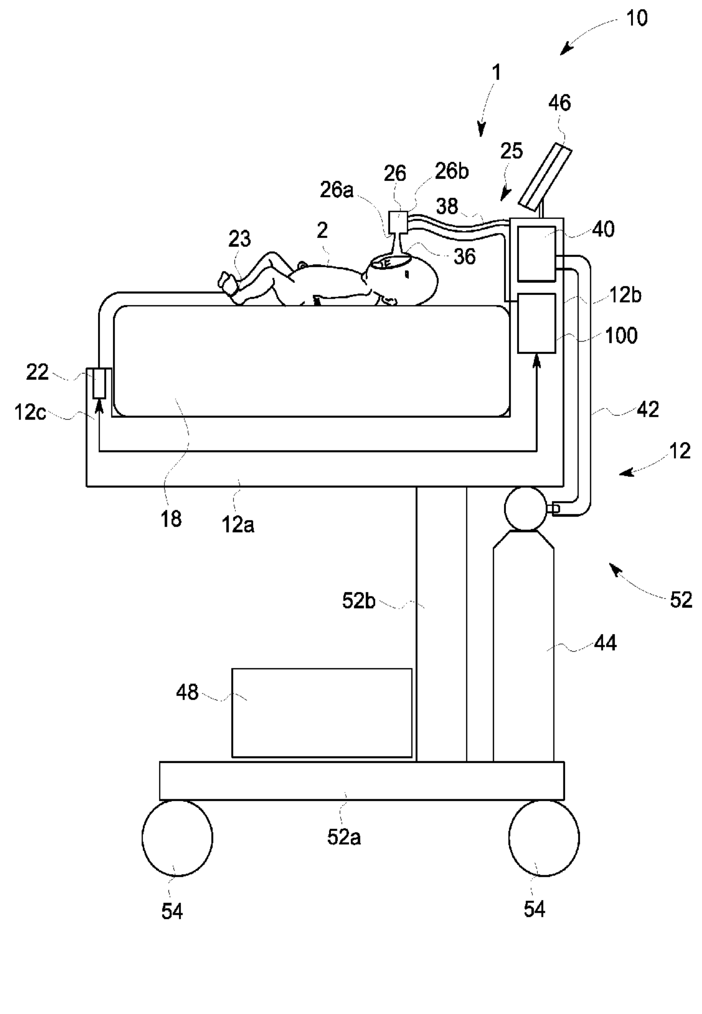
A61B 5/087	(2006.01)
A61B 5/08	(2006.01)
A61B 5/145	(2006.01)
A61M 16/08	(2006.01)
A61B 5/00	(2006.01)
A61M 16/06	(2006.01)
A61B 5/091	(2006.01)
A61M 16/00	(2006.01)

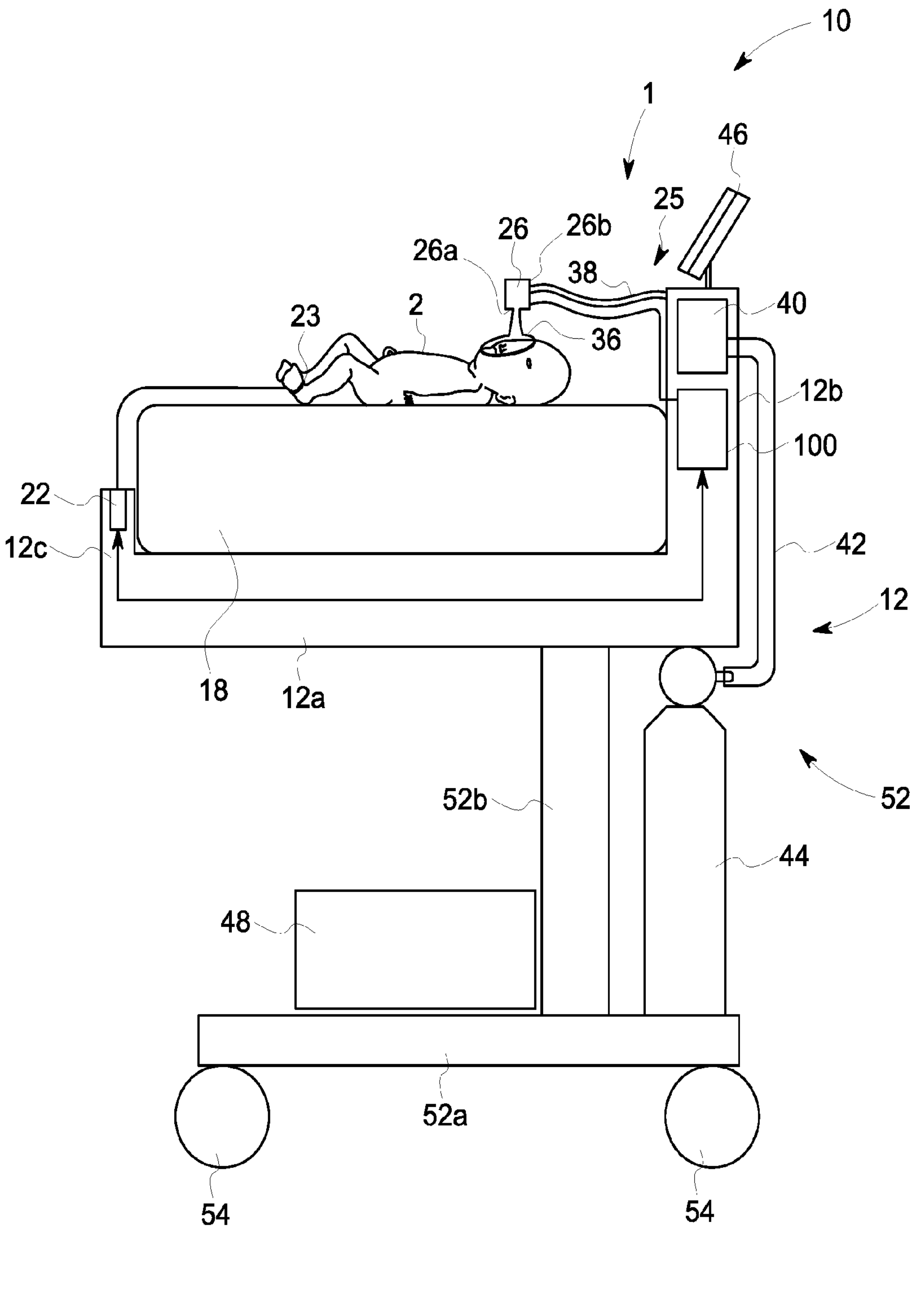
(52) **U.S. Cl.**

CPC ***A61B 5/087*** (2013.01); ***A61M 16/06*** (2013.01); ***A61B 5/0816*** (2013.01); ***A61B 5/082*** (2013.01); ***A61B 5/091*** (2013.01); ***A61B 5/14542*** (2013.01); ***A61M 16/0875*** (2013.01); ***A61B 5/0022*** (2013.01); ***A61B 5/742*** (2013.01); ***A61B 5/7275*** (2013.01); *A61M 2016/0033* (2013.01); *A61M 2205/3331* (2013.01); *A61M 2205/3368* (2013.01); *A61M 2230/432* (2013.01); *A61M 2230/435* (2013.01)

(57) ABSTRACT

A newborn respiration monitoring system includes a flow sensor that measures a gas flow and a CO_2 sensor that measures a CO_2 within the breathing circuit for an infant. The system further includes a resuscitation module executable on a processor of a computing system to receive the flow measurement and the CO_2 measurement and determine respiratory information for the infant. A digital display is communicatively connected to the computing system and displays the respiratory information.





10
1
46
25
26
26b
26a
38
40
23
2
36
12b
100
22
12c
42
12
18
12a
52
52b
44
48
52a
54
54

FIG. 1

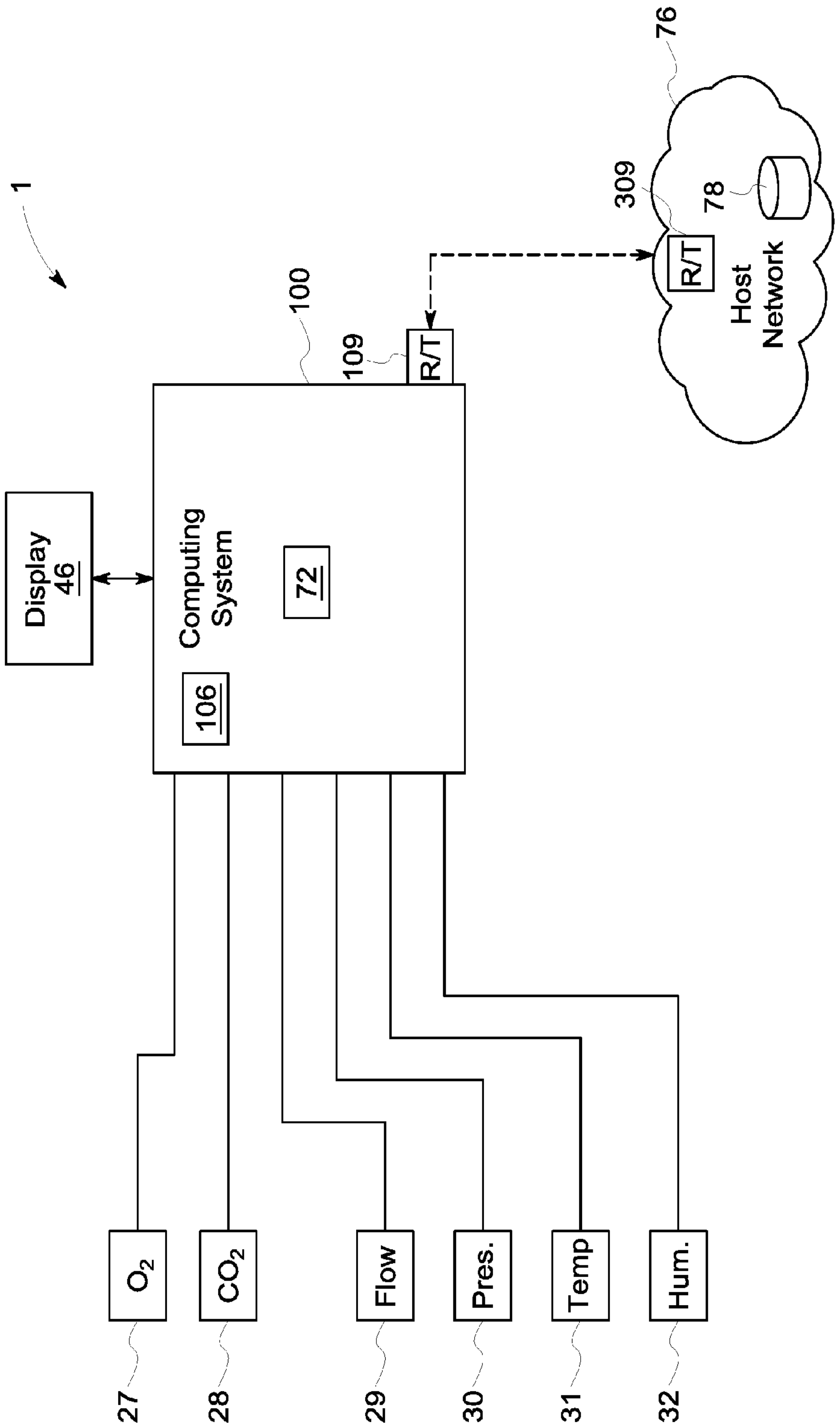

1
Display
46
Computing
System
106
72
100
109
R/T
309
R/T
78
Host
Network
76
O_2
CO_2
Flow
Pres.
Temp
Hum.
27
28
29
30
31
32

FIG. 2

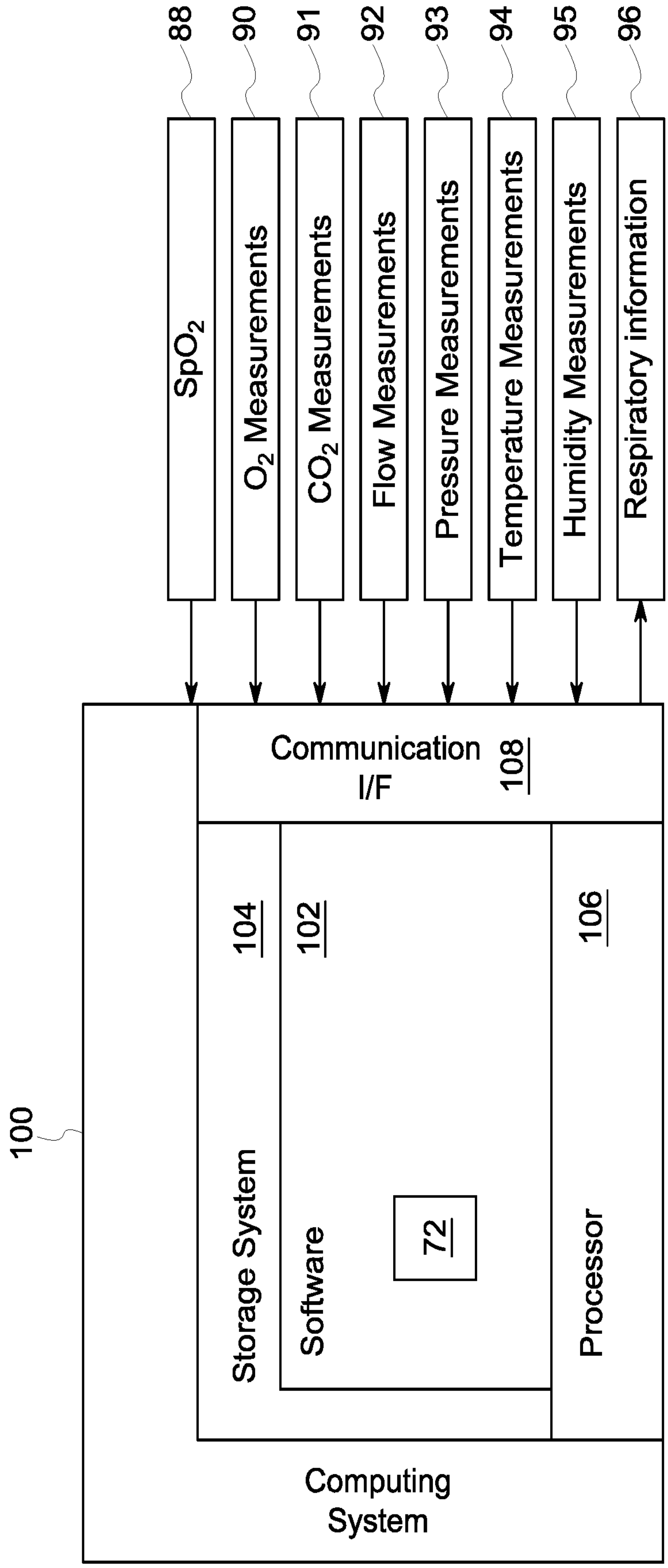

88
90
91
92
93
94
95
96
SpO_2
O_2 Measurements
CO_2 Measurements
Flow Measurements
Pressure Measurements
Temperature Measurements
Humidity Measurements
Respiratory information
Communication I/F
108
100
104
102
106
Storage System
Software
72
Processor
Computing System

FIG. 3

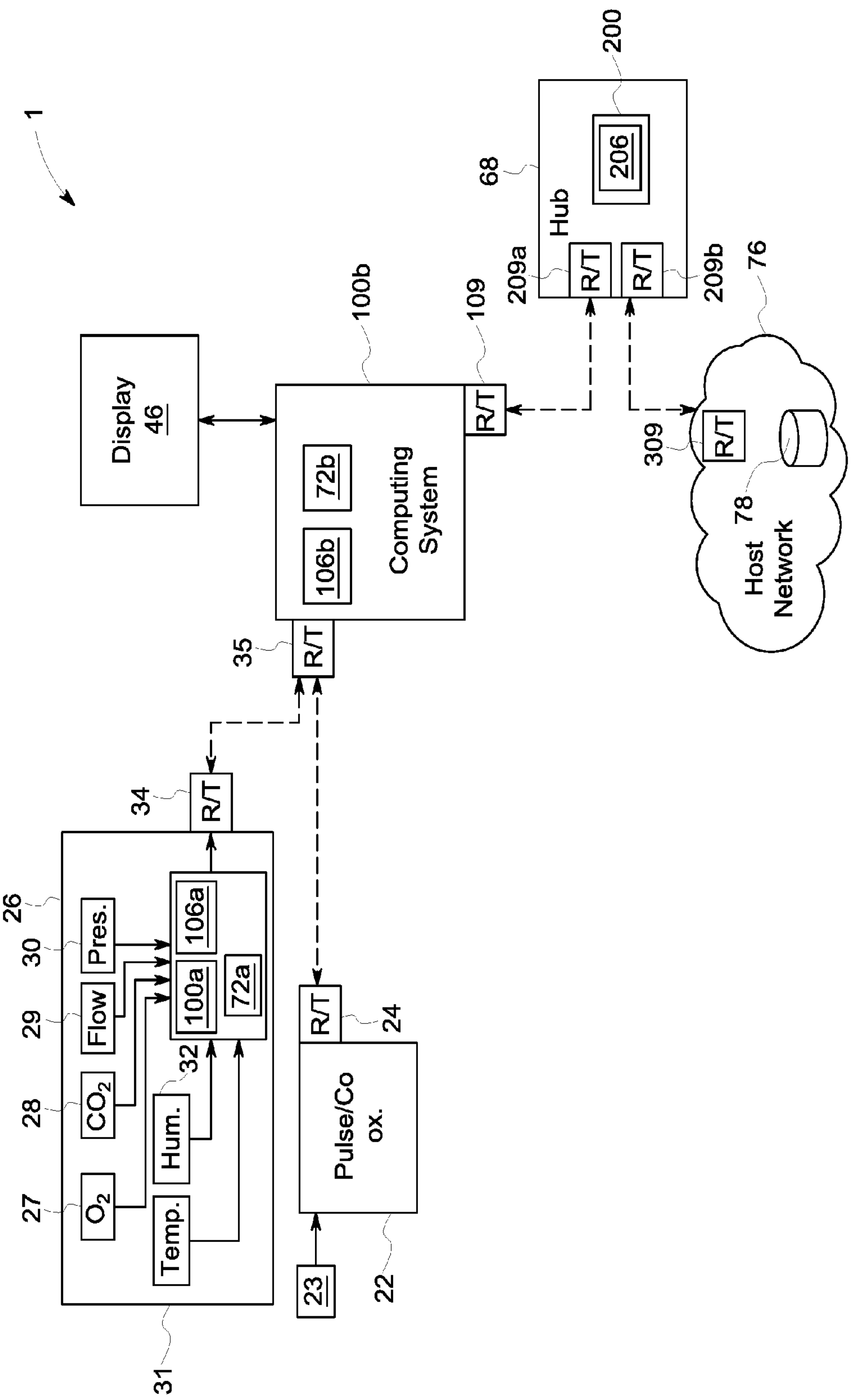

1
Display
46
Computing
System
106b
72b
100b
109
R/T
Hub
206
200
68
R/T
209a
R/T
209b
76
Host
Network
R/T
309
78
35
R/T
34
R/T
26
Pres.
30
Flow
29
CO_2
28
O_2
27
Hum.
32
Temp.
106a
100a
72a
31
R/T
24
Pulse/Co
ox.
22
23

FIG. 4

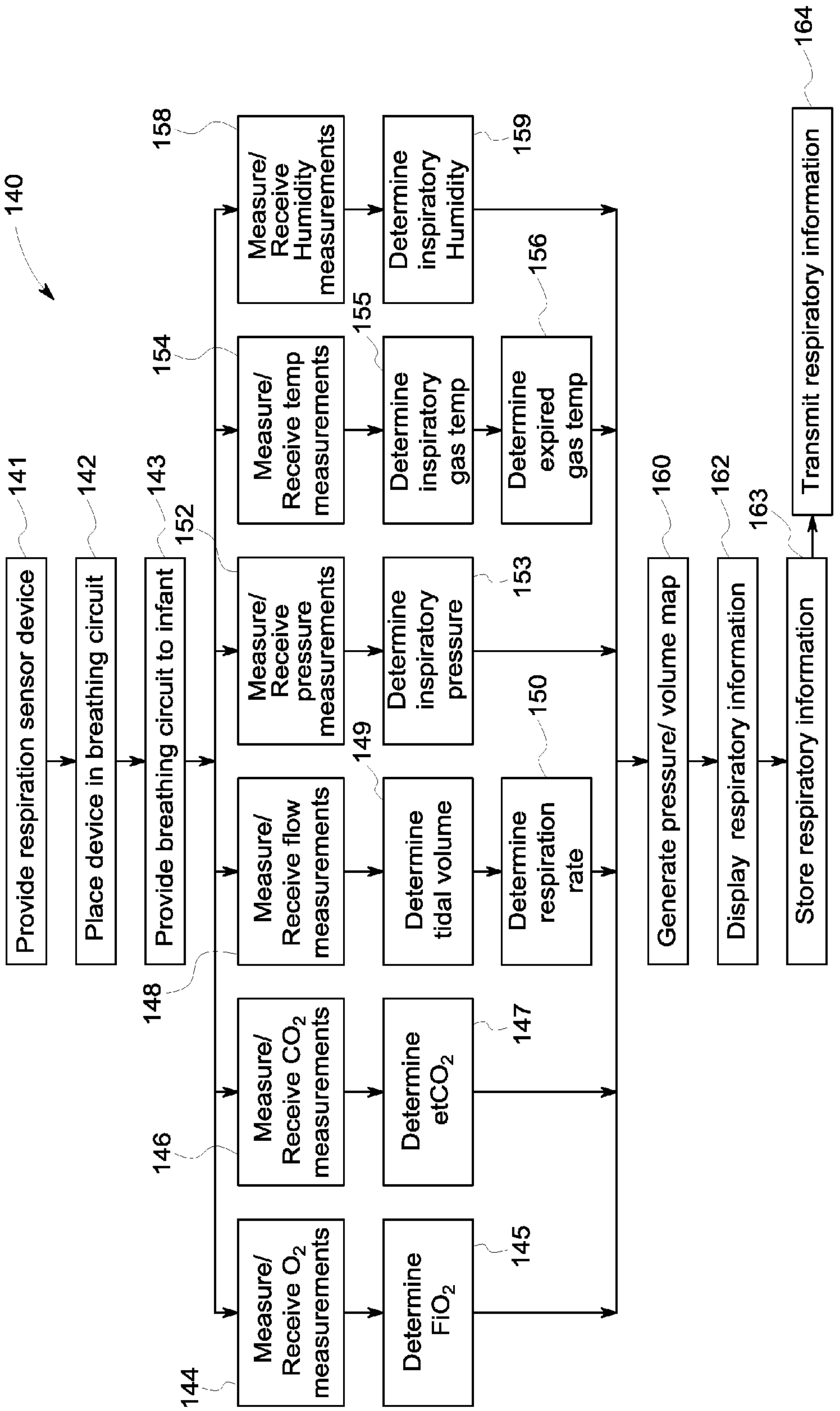

140
Provide respiration sensor device
141
Place device in breathing circuit
142
Provide breathing circuit to infant
143
Measure/ Receive O2 measurements
144
Determine FiO2
145
Measure/ Receive CO2 measurements
146
Determine etCO2
147
Measure/ Receive flow measurements
148
Determine tidal volume
149
Determine respiration rate
150
Measure/ Receive pressure measurements
152
Determine inspiratory pressure
153
Measure/ Receive temp measurements
154
Determine inspiratory gas temp
155
Determine expired gas temp
156
Measure/ Receive Humidity measurements
158
Determine inspiratory Humidity
159
Generate pressure/ volume map
160
Display respiratory information
162
Store respiratory information
163
Transmit respiratory information
164

FIG. 5

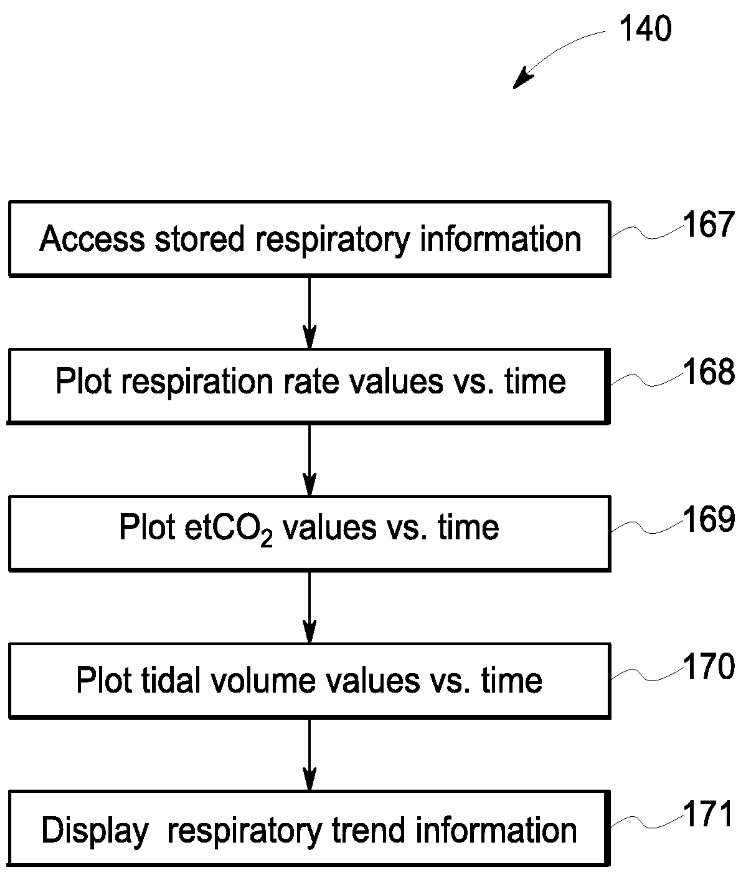

140
Access stored respiratory information
167
Plot respiration rate values vs. time
168
Plot etCO2 values vs. time
169
Plot tidal volume values vs. time
170
Display respiratory trend information
171

FIG. 6

NEWBORN RESPIRATION MONITORING SYSTEM AND METHOD

BACKGROUND

[0001] The present disclosure relates to the field of newborn care, and more specifically to systems and methods for providing respiratory care to newborn infants immediately upon birth.

[0002] At the time of birth, infants need immediate assessment and care, including assessment of heart and respiratory function. Infant patients can experience relatively rapid changes in condition, especially immediately after birth. Depending on the infant's condition, various therapies may be provided, including resuscitation or other respiratory care.

SUMMARY

[0003] This Summary is provided to introduce a selection of concepts that are further described below in the Detailed Description. This Summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to be used as an aid in limiting the scope of the claimed subject matter.

[0004] In one embodiment, a newborn respiration monitoring system includes a flow sensor that measures a gas flow and a CO_2 sensor that measures a CO_2 within the breathing circuit for an infant. The system further includes a resuscitation module executable on a processor of a computing system to receive the flow measurement and the CO_2 measurement and determine respiratory information for the infant. A digital display is communicatively connected to the computing system and displays the respiratory information.

[0005] One embodiment of a method of monitoring newborn infant respiration includes measuring a gas flow with a flow sensor in a breathing circuit for the infant, communicating the flow measurement to a computing system, measuring a CO_2 with a CO_2 sensor in a breathing circuit for the infant, and communicating the CO_2 measurement to the computing system. The method further includes determining respiratory information for the infant with the computing system based on at least the flow measurement and the CO_2 measurement, and displaying the respiratory information for the infant on a digital display communicatively connected to the computing system.

[0006] Various other features, objects, and advantages of the invention will be made apparent from the following description taken together with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The present disclosure is described with reference to the following Figures.

[0008] FIG. **1** depicts one embodiment of a newborn respiration monitoring system incorporated in a mobile newborn care bed.

[0009] FIG. **2** is a schematic depicting one embodiment of a newborn respiration monitoring system.

[0010] FIG. **3** is a schematic depicting one embodiment of a computing system for a newborn respiration monitoring system.

[0011] FIG. **4** is a schematic depicting another embodiment of a newborn respiration monitoring system.

[0012] FIG. **5** is a flowchart depicting one embodiment of a method of monitoring newborn infant respiration.

[0013] FIG. **6** depicts another embodiment of a method of monitoring newborn infant respiration.

DETAILED DESCRIPTION

[0014] In light of their experimentation and research in the relevant field, the present inventors have recognized that clinicians providing care to infants at birth are often seeking more guidance for providing safe, non-invasive respiratory and resuscitative care to infants, such as to reduce barotrauma and volutrauma, and to reduce or delay use of invasive ventilation as much as possible in the delivery room. Current systems for providing newborn resuscitation do not enable sufficient respiratory monitoring necessary to provide consistent and optimal resuscitative care to a newborn, including failing to provide barometric, volumetric, and inspiratory/expiratory gas content measurements. In light of these problems and needs in the relevant field recognized by the inventors, they developed the disclosed newborn respiration monitoring system and method, including sensor systems for monitoring non-invasive respiratory therapy providing positive pressure ventilation and/or continuous positive airway pressure.

[0015] Further, according to long-standing care standards, an infant's umbilical cord is cut immediately upon delivery and the infant was placed on a patient care surface spaced away from the mother to assess and provide any needed therapy, such as respiratory support. In such instances, babies were removed from the delivery location and placed on a bassinet or infant bed, often containing a radiant warmer. Currently available infant beds and radiant warmers are configured to be positioned in a corner of a delivery room so as not to crowd the space next to the mother. Moreover, most infant care beds and radiant warmers are one, integrated, bulky device, where the bassinette is built into the warmer. Resuscitation equipment and/or monitoring equipment, if any, is either integrated into the warming device or positioned near the infant bed/radiant warmer away from the delivery location.

[0016] However, care standards are trending towards maintaining the infant at the birthing site to the extent possible in order to allow delayed cord clamping and delayed cutting for several minutes so that the blood in the placenta is transferred to the baby. Accordingly, through their experimentation and research in the relevant field, the present inventors have recognized such delated cord clamping and other modern care standards for newborn infants immediately after birth have made current radiant warmer and resuscitation platform technology challenging. The inventors have recognized that a device is needed to provide diagnosis and therapy to a newborn infant immediately next to the mother and at the site of birth so that such therapy can be administered before and/or during the cord clamping. Further, the inventors have recognized that devices and systems are needed that provide monitoring and resuscitation care for infants easily and with minimal attachment of devices to the baby. Further, the inventors have recognized that devices and systems are needed that provide immediate and accessible display of multiple relevant respiration-related parameters to clinicians providing care, and also seamless transmission and storage and of such data to the patient's healthcare records.

[0017] In view of their recognition of problems and needs in the relevant field, the inventors developed the disclosed newborn respiration monitoring system and method. The newborn respiration monitoring system is mobile and able to be located at a delivery location of an infant to enable a clinician to provide respiration monitoring and/or resuscitative care to an infant immediately upon birth at the birthing location, including before and during cord clamp.

[0018] FIG. **1** depicts one embodiment of a newborn respiration monitoring system **1**, which in the depicted embodiment is incorporated into a bassinette of a mobile newborn bed. FIGS. **2** and **3** provide schematic diagrams of various embodiments of the newborn respiration monitoring system **1**, which may be a relatively small and portable system separate and apart from an infant bed and able to be transported to a delivery location of an infant. The newborn respiration monitoring system **1** includes one or more sensors to measure parameters within a breathing circuit **25** for the infant **2**. Examples of the one or more sensors include an O_2 sensor **27**, a CO_2 sensor **28**, a flow sensor **29**, a pressure sensor **30**, a temperature sensor **31**, and a humidity sensor **32**. Each of the sensors measures a value within the breathing circuit **25** and communicates the value to a computing system **100**. The computing system **100** includes a resuscitation module **72** executable on one or more processors **106** to determine respiratory information **96** for the infant **2**. The computing system **100** may control a digital display **46** to display some or all of the respiratory information **96**, such as to provide information to a clinician caring for the infant **2** regarding the infant's respiratory health and/or regarding the respiratory intervention being provided to the infant **2** via the breathing circuit **25**. Additionally, the computing system **100** may communicate the respiratory information to a host network **76** and/or to an intermediary, such as hub device **68**.

[0019] The newborn respiration monitoring system **1** may be a stand-alone system or set of devices that transportable to a location where respiratory intervention is being provided to an infant **2** with a respiratory device **40**. Alternatively, the newborn respiration monitoring system **1** may be incorporated into another device for providing infant care, such as into a respirator device, a fetal monitor, or another device for monitoring the physiological well being of a newborn infant **2**. FIG. **1** exemplifies an embodiment where the newborn respiration monitoring system **1** is incorporated into a bassinette **12** of a mobile newborn bed **10**. The newborn bed **10** is preferably portable and small enough and agile enough to be transported to and located at the delivery location of the infant so that respiratory care and respiration monitoring can be provided to the infant **2** at the delivery location where the infant is delivered by the mother.

[0020] The mobile newborn bed **10** has a bassinet **12** and a frame **53**. The bassinet contains a mattress **18** on which the infant **2** is placed. The mattress **18** is preferably a flat or slightly concave cushioned surface, but can be any flat or curved surface capable of receiving the infant **2**. The frame **52** is underneath the bassinet **12** and supports the bassinet **12**. The frame includes a base frame portion **52*a*** connecting to one or more wheels **54** that allow the mobile newborn bed **10** to be easily moved. The frame **52** also includes a vertical frame portion **52*b*** that elevates and attaches to the bassinet **12**. In various embodiments, the vertical frame portion **52*b*** may be adjustable to adjust the height of the bassinet **12**. The base frame portion **52*a*** may be configured to support various elements comprising part of the mobile newborn bed **10**, such as one or more batteries **48** and/or gas supply tanks **44**.

[0021] In the depicted embodiment, the bassinet **12** includes a bottom portion **12*a*** supporting the mattress **18**, and also includes a head portion **12*b*** adjacent to one side of the mattress **18** and a foot portion **12*c*** adjacent to another side of the mattress **18**. In the depicted embodiment, the head portion **12*b*** houses or comprises computing system **100** and respirator **40**, and the foot portion **12*c*** houses or comprises pulse oximeter device **22**. In other embodiments, such devices may be housed or incorporated at other locations on the mobile newborn bed **10** or may be provided separately but in conjunction with the mobile newborn bed **10**.

[0022] Devices and systems for providing resuscitation and other respiratory therapy to an infant **2** may be associated with or incorporated into the newborn respiration monitoring system **1**, which includes sensors placed within a breathing circuit **25**. A breathing circuit **25** for providing gas to the infant **2** may include a ventilator device **40**, such as a continuous positive airway pressure (CPAP) device, a positive pressure ventilation (PPV) device, or a positive end-expiratory pressure (PEEP) device (or a ventilator device providing all three respiratory therapies). In the embodiment depicted in FIG. **1**, the ventilator device **40** receives a gas supply from supply tube **42** connected to gas supply tank **44** supported on the base frame portion **52*a***. The ventilator device **40** regulates the gas supply as appropriate to provide resuscitative or respiratory assistance to the infant **2**. The ventilator device **40** connects to the breathing tube **38** to supply gas to the infant through mask **36** applied over the infant's nose and mouth. In other embodiments, the breathing tube **38** may deliver gas to the infant **2** via a nasal cannula or by some other delivery means.

[0023] The breathing circuit **25** is equipped with sensors for measuring parameters relevant to the infant's respiration, which may be provided in the mask **36**, breathing tube **38**, or at the connection of the mask **36** and the breathing tube **38**. Various sensors may be incorporated into the breathing circuit **25**, such as a CO_2 sensor **28** that measures CO_2 in gas expired by the infant **2**, an O_2 sensor **27** that measures O_2 in gas inspired by the infant **2**, a flow sensor **29** that measures gas flow at a location in the breathing circuit **25**, a pressure sensor **30** that measures pressure at a location in the breathing circuit **25**, a temperature sensor **31** measuring temperature of expired and/or inspired gas within the breathing circuit **25**, and/or a humidity sensor **32** measuring humidity of inspired gas within the breathing circuit **25**. More specifically, the O_2 sensor **27** supplies O_2 measurements **90**, CO_2 sensor **28** supplies CO_2 measurements **91**, flow sensor **29** supplies flow measurements **92**, pressure sensor **30** supplies pressure measurements **93**, temperature sensor **31** supplies temperature measurements **94**, and humidity sensor **32** supplies humidity measurements **95**.

[0024] As shown in FIG. **1**, the mobile newborn bed **10** may include a battery **48** to power the various devices thereon, including some or all of the various sensing devices, the computing system **100**, the ventilator device **40**, and/or the digital display **46**. The battery **48** may be positioned on the base frame portion **52*a***, for example, and in such a location to be easily accessed in order to recharge or replace the battery **48**. The charge status of the battery **48** may be monitored by a power control module, such as may be provided separately from and in communication with, or otherwise incorporated into, the computing system **100**. Further, the computing system **100** may provide a battery status notification, such as on digital display **46**, regarding the charge of the battery **48** on the digital display **46** so that a clinician or other user will be able to determine the charge level of the battery **48**.

[0025] In various embodiments, newborn respiration monitoring system **1** may be configured with any one or more of the aforementioned sensors to provide respiration parameter measurements **90-95** from the breathing circuit **25**, and such respiration parameter measurements may include, but are not limited to, the aforementioned measurements. The respiration parameter measurements **90-95** are communicated to computing system **100** by wired or wireless means. For example, each of the sensors **27-32** may be incorporated into the patient-end of the breathing circuit **25**, such as in the mask **36**, breathing tube **38**, or at a junction therebetween, and such sensors may connect by wires running along the breathing tube **38**. In some embodiments such wires may be incorporated into the length of the breathing tube **38**. In other embodiments, one or more of the sensors **27-32** may be equipped with or associated with a wireless transmitter to wirelessly transmit the respiration parameter measurements **90-95** to the computing system **100**, and in such embodiments may also be associated with or include an analog-to-digital converter to digitize analog signals before wireless transmission.

[0026] For example, each of the aforementioned sensors **27-32** may be contained in a respiration sensor device **26** positioned in the breathing circuit **25**, such as between the mask **36** and the breathing tube **38**. FIG. **4** schematically depicts an exemplary embodiment of the respiration sensor device **26** containing O_2 sensor **27**, CO_2 sensor **28**, flow sensor **29**, pressure sensor **30**, temperature sensor **31**, and humidity sensor **32**. For instance, the respiration sensor device **26** may be configured to communicate the respiration parameter measurements **90-95** from all of the sensors **27-32** to the computing system **100**. The respiration sensor device **26** may communicate wirelessly or by wires that extend to the computing system **100**. In the embodiment of FIG. **1**, wires (such as extending along and/or embedded into the breathing tube **38**) connect one or more sensors **27-32** to a receiving connector in the bassinet **12**, or otherwise electrically connect to the computing system **100**. In other embodiments, such as that depicted in FIG. **4**, the respiration sensor device **26** may communicate the respiration parameter measurements **90-95** to a wireless receiver associated with the computing system **100**.

[0027] The computing system **100** may be communicatively connected (i.e. connected by physical or wireless means so as to be able to communicate messages to or with another device) to digital display **46** to communicate display commands thereto, such as to display the respiratory information **96** thereon. Accordingly, the digital display **46** may display the infant's respiration rate, FiO_2, $etCO_2$, or any of numerous other respiratory information **96** to a clinician while the clinician is providing medical care to the infant **2**. Likewise, the computing system **100** may control the digital display **46** to display notifications of inappropriate respiratory intervention, poor respiratory health or respiratory events, such as to provide a visual alert when one or more values in the respiratory information **96** is outside of a predetermined range or changes by more than a predetermined amount over a short period of time.

[0028] The digital display **46** may be any digital display device known in the art and may be a housed separately from the computing system **100** or housed together with the computing system **100**. In the context of the FIG. **1** embodiment, the digital display may be fixed to the bassinet **12**, such as to the head portion **12***b* of the bassinet **12**, in a way that is visible to clinicians providing care to the infant **2**. Alternatively, the digital display **46** may be a separable or completely separate device from the bassinette **12**, such as a tablet or mobile computer. In still other embodiments, the digital display **46** may be a display of another device networked with the computing system **100** of the newborn respiration monitoring system **1**, such as a display of a fetal monitor. Likewise, in an embodiment where the newborn respiration monitoring system is incorporated into or with another monitoring device, the computing system **100** may be a shared computing system with multiple monitoring functions.

[0029] In an embodiment where the newborn respiration monitoring system **1** is a stand-alone device, the computing system **100** may be housed separately from or together with the digital display **46** and the sensors **27-32**. For example, the computing system **100** may be incorporated into the same housing as the digital display **46**, or it may be partially or entirely incorporated into a housing with one or more of the sensors **27-32**. FIG. **4** exemplifies one embodiment where the computing system **100** comprises a first computing system portion **100***a* incorporated into respiration sensor device **26** and a second computing system portion **100***b* communicatively connected to digital display **46**. As described further herein, the various functions of the computing system **100** and resuscitation module **72** may be divided between multiple locations and executed on different processors.

[0030] The newborn respiration monitoring system **1** may further include a pulse oximeter device **22**, including sensor **23** attachable to the patient that determines an estimate of oxygen saturation (SpO_2) value **88** and transmits the SPO_2 value **88** to the computing system **100**. The pulse oximeter **22** may transmit the SpO_2 value by wired or wireless means, various examples of which are provided herein. In an embodiment like that of FIG. **1** where the newborn respiration monitoring system **1** is incorporated into a mobile newborn bed **10**, the pulse oximeter **22** may be incorporated into the bassinet **12**, such as in the foot portion **12***c*. In other embodiments, the pulse oximeter may be a separate device that may be kept in proximity of the bassinet **12** and may be wirelessly paired with the computing system **100**. As exemplified in the embodiment of FIG. **4**, the pulse oximeter **22** is provided with receiver/transmitter **24**, which communicates with receiver/transmitter **35** of the second computing system portion **100***b*.

[0031] The sensor **23** may be any sensor device capable of measuring the infant's peripheral oxygen saturation or other hemoglobin saturation parameters, such as a disposable adhesive sensor device configured to wrap around the infant's foot. The sensor **23** may include a wire connecting to the pulse oximeter **22**. In still other embodiments, the physical circuitry and software of the pulse oximeter **22** may be incorporated within the computing system **100**, and thus the sensor **23** may communicate measurements related to O_2 saturation directly to the computing system **100** for determination of SpO_2 values **88** for the infant **2**.

[0032] Upon receipt or determination of the SpO_2 value **88** for the infant **2**, the computing system **100** may transmit the SpO_2 value **88** to the hub device **68**, or directly to a host network **76**. Further, the computing system **100** may send control signals to the digital display **46** in order to display the SpO_2 value **88** thereon. Alternatively or additionally, the device **22** may be a co-oximeter device that measures and determines one or more of SpO2, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and/or total hemoglobin concentration (g/dl SpHb). For instance, the co-oximeter device **22** may be a Rainbow SET Pulse CO-Oximeter by Masimo Corporation of Irvine, Calif. The SpO_2, SpCO, SpMet and/or SpHb can relate to respiration and can provide useful information regarding what and how respiratory intervention should be applied. Accordingly, the newborn respiration monitoring system **1** may incorporate such measurements in its overall display of information to a clinician providing care for the infant **2**, so that the infant's condition can be immediately assessed and it can be determined what resuscitative care is necessary and appropriate.

[0033] As described herein, the digital display **46** may be controlled by the computing system **100** to provide various health information for the patient, including the respiratory information **96**, SPO_2 value **88**, or any other relevant value. Additionally, the digital display **46** may provide a user input device, such as via a touchscreen, to provide control input to the computing system **100** and/or any other system or device incorporated in or associated with the newborn respiration monitoring system **1**. Accordingly, in various embodiments, multiple systems and devices may connect directly to the digital display **46** and be capable of providing control signals to the digital display **46**. For example, the ventilator device **40** may connect to the digital display **46** and the digital display **46** may provide a user interface to control the ventilator device **40**. Such connectivity may be provided directly between the ventilator device **40** and the digital display **46**, or may be routed through the computing system **100**, which may provide a central control for multiple devices, such as including the ventilator device **40**.

[0034] Referring to FIGS. **2** and **3**, the computing system **100** may include a software module stored in memory and executable on a processor **106** within the computing system **100**, a resuscitation module **72**, configured to process one or more of the respiration parameter measurements **90-95** to generate respiratory information **96** regarding the respiratory status of the infant **2**. For example, the resuscitation module **72** may determine respiratory information **96** including an inspired O_2 indicator, such as fraction of inspired oxygen (FiO_2). Alternatively or additionally, respiratory information **96** determined by the resuscitation module **72** may include an end tidal CO_2 ($etCO_2$) based on the CO_2 measurements **91**. Likewise, resuscitation module **72** may calculate tidal volume based on the flow measurements **92**, such as by calculating volume as an integral of the flow curve and/or sum of the flow measurements **92** during the inspiratory cycle, and/or intake air pressure based on the pressure measurements **93**. Alternatively or additionally, the resuscitation module **72** may utilize the temperature measurements **94** to determine the temperature of the inspired gas and/or the expired gas. Such temperature measurements **94** may be used to regulate the temperature of the gas provided to the infant **2** and/or to determine information about the temperature of the infant **2**. The resuscitation module **72** may utilize the humidity measurements **95** to determine a humidity of the gas being provided to the patient, and such information may be used to control the same. Any one of the aforementioned values may be included in the respiratory information **96**, which may also include any number of alternative or additional parameters (e.g., respiration rate) outputted by the resuscitation module **72**, and such respiratory information **96** may be transmitted to a hub device **68** and/or a host network **76** for storage in the patient's medical record in database **78**. Alternatively or additionally, some or all of the respiratory information **96** may be displayed on the digital display **46**.

[0035] FIG. **4** schematically depicts an exemplary embodiment of the newborn respiration monitoring system **1** that includes a respiration sensor device **26** containing O_2 sensor **27**, CO_2 sensor **28**, flow sensor **29**, pressure sensor **30**, temperature sensor **31**, and humidity sensor **32**. The respiration sensor device **26** further includes a first computing system portion **100*a*** having processor **106*a*** and first resuscitation module portion **72*a*** executed on processor **106*a*** receives the respiration parameter measurements **90-95** from the sensors **27-31**. A person having ordinary skill in the art will understand in light of this disclosure that computing system portions **106*a*** and **106*b*** may be independent computing systems communicatively connected as part of the newborn respiration monitoring system **1** and to execute the methods **140** described herein. Likewise, a person having ordinary skill in the art will understand in light of this disclosure that the computing system portions **100*a***, **100*b*** may be housed in any of various components within the system **1**, such as in the respirator device **40** or incorporated as part of another fetal monitor or fetal care device or system. The first computing system portion **100*a*** and resuscitation module portion **72*a*** may filter and condition the signals for transmission to the second computing system portion **100*b*** and second resuscitation module portion **72*b***. A person having ordinary skill in the art will understand in light of this disclosure that such sensors **27-32** may be analog or digital, producing analog or digital respiration parameter measurements **90-95**, and thus analog-to-digital conversion circuitry may be incorporated in the respiration sensor device **26** as necessary to digitize measurements from analog sensor devices. The first resuscitation module portion **72*a*** may process some or all of the respiration parameter measurements **90-95** to respiratory information **96** for the infant.

[0036] The first computing system portion **100*a*** and first resuscitation module portion **72*a*** communicates the respiration parameter measurements **90-95** and/or respiratory information **96** via wireless communication protocol to second computing system portion **100*b*** through wireless receiver/transmitter **34**. Transmissions from the wireless receiver/transmitter **34** are received by a wireless receiver/transmitter **35** associated with the computing system **100**. The wireless receiver/transmitters **34** and **35** may communicate via any wireless protocol, and relatively short range wireless protocols, such as Bluetooth, Bluetooth low energy (BLE), ANT, ZigBee, or a near field communication (NFC) protocol, may be especially useful in embodiments of the newborn respiration monitoring system **1** where the distance between the respiration sensor device **26** and the second computing system portion **100*b*** are expected to be small. In other embodiments, the communication may be via network protocols appropriate for longer-range wireless transmissions, such as on the wireless medical telemetry service

(WMTS) spectrum or on a Wi-Fi-compliant wireless local area network (WLAN). In still other embodiments, the receiver/transmitters **109** and **209***a* may be capable of switching between two or more wireless communication protocols, such as to optimize data communication based on the situation.

[0037] The respiration sensor device **26** may be configured to be positionable between the mask **36** and the breathing tube **38**. Referring to FIG. **1**, the respiration sensor device **26** may have a first end **26***a* connectable to mask **36** (or other gas delivery means, such as nasal prongs) and a second end **26***b* connectable to breathing tube **38**. Accordingly, each end **26***a*, **26***b* may have appropriate connecting means to facilitate such connection within the breathing circuit. Furthermore, the first end **26***a* and second end **26***b* may be configured in any position with respect to one another on the respiration sensor device, and may be positioned oppositely, perpendicularly, or adjacently to one another on the respiration sensor device **26**. In another embodiment, the respiration sensor device **26** may be incorporated into the mask **36**, such that the respiration sensor device **26** is a single, inseparable element with the mask **36**.

[0038] In FIG. **4**, the second computing system portion **100***b* and the second resuscitation module portion **72***b* receive the respiration parameter measurements **90-95** and/or respiratory information **96** and conduct further processing as required to generate further respiratory information **96** and/or conduct further assessment of the data. For example, the second resuscitation module portion **72***b* may determine one or more respiratory information trends, such as by plotting some or all of the respiratory information **96** with respect to time. The second resuscitation module portion **72***b* may further control the digital display **46** to display some or all of the respiratory information **96** or respiratory information trends. The second computing system portion **100***b* communicates wirelessly to a hub device **68**, which in turn communicates wirelessly to host network **76**. The hub device **68** may be may be positioned at any location within communication distance of the second computing system portion **100***b*. The hub device **68** may be provided by a mobile computing device, such as a laptop, tablet, smart phone, or the like. For example, a software application may be provided to allow a clinician's tablet or smart phone to act as the hub device **68**. In still other embodiments, the hub device **68** may be a fetal monitoring unit, and thus the second computing system portion **100***b* may communicate the respiratory information **96** and or respiration parameter measurements **90-95** to the fetal monitoring unit for transmission to the host network **76**. In such an embodiment, the fetal monitoring unit may also provide the digital display **46** to display some or all of the respiratory information **96**, etc.

[0039] In an embodiment incorporating a hub device **68**, the hub device **68** has a computing system **200** equipped with a processor **206**. The hub computing system **200** is equipped to communicate with the computing system **100** and the host network **76** via receiver/transmitters **209***a* and **209***b* respectively. Wireless communication between the hub device **68** and the host network **76**, or between the computing system **100** and the host network **76**, may accomplished by any wireless protocols known in the relevant art. In the depicted embodiments, the computing system **100** has receiver/transmitter **109** configured to communicate with receiver/transmitter **209***a* on the hub device **68**. The various receiver/transmitters **24**, **34**, **35**, **109**, **209***a*, **209***b*, **309** may include separate receiving and transmitting devices or may include an integrated device providing both functions, such as a transceiver. The computing system **100** and hub device **68**, via respective receiver/transmitters **109** and **209***a*, may be configured as medical body area network (MBAN) devices. In other embodiments, the receiver/transmitters **109** and **209***a*, and/or **209***b* and **309** may communicate via other short range radio protocols, such as Bluetooth, Bluetooth Low Energy (BLE), ANT, ZigBee, or NFC. In other embodiments, the communication may be via network protocols appropriate for longer-range wireless transmissions, such as on the wireless medical telemetry service (WMTS) spectrum or on a Wi-Fi-compliant wireless local area network (WLAN). In still other embodiments, the respective receiver/transmitters may be capable of switching between two or more wireless communication protocols, such as to optimize data communication based on the situation.

[0040] In other embodiments, where the computing system **100** communicates directly with the host network **76** via communication between receiver/transmitters **109** and **209**, such transmission may be via network protocol appropriate for longer-range wireless transmissions, such as on the WMTS spectrum or on a WLAN, as described above. The host network **76** may be, for example, a local computer network having servers housed within a medical facility where the infant **2** is born, or it may be a cloud-based system housed by a cloud computing provider. The host network **76** may include a medical records database **78** housing the medical records for the infant **2**, which may be updated to store the information transmitted by the computing system **100** and/or the hub device **68**.

[0041] FIG. **3** provides a system diagram of a computing system **100** having resuscitation module **72** executable to determine respiratory information **96**. Furthermore, the resuscitation module **72** executable to store the respiratory information **96** in storage system **104** of the computing system **100** so that such information may be accessed at a later time, such as to generate trend plots. Likewise, resuscitation module **72** may be executable to store the measurement data from the sensors **27-32**, in storage system **104** of the computing system **100** so that such information may be accessed at a later time, such as to generate trend plots. For example, such information may be accessed by the various modules and/or by clinicians to determine whether the infant **2** is ready for discharge or whether certain physiological indicators indicate that continued care is needed, such as whether the infant **2** is experiencing continued apnea events.

[0042] Computing system **100** includes a processor **106**, storage system **104**, software **102**, and communication interface **108**. The processor **106** loads and executes software **102** from the storage system **104**, including the resuscitation module **72**, which is an application within the software **102**. The resuscitation module **72** includes computer-readable instructions that, when executed by the computing system **100** (including the processor **106**), direct the processor **106** to operate as described herein.

[0043] Although the computing system **100** as depicted in FIG. **3** includes one software **102** encapsulating one resuscitation module **72**, it should be understood that one or more software elements having one or more modules may provide the same operation. Similarly, while description as provided herein refers to one computing system **100** and a processor **106**, it is to be recognized that the methods and systems described herein be executed using two or more computing systems (processors, storage systems, etc.), which may be communicatively connected, and such implementations (which are exemplified in the embodiment of FIG. **4**) are considered to be within the scope of the description.

[0044] Processor **106** may comprise a microprocessor and other circuitry that retrieves and executes software **102** from storage system **104**. Processor **106** can be implemented within a single processing device but can also be distributed across multiple processing devices or sub-systems that cooperate in executing program instructions. Examples of processor **106** include general purpose central processing units, application specific processors, and logic devices, as well as any other type of processing device, combinations of processing devices, or variations thereof.

[0045] The storage system **104** may comprise any storage media, or group of storage media, readable by processor **106** and capable of storing software **102**. The storage system **104** 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. Storage system **104** can be implemented as a single storage device but may also be implemented across multiple storage devices or sub-systems. Storage system **104** may further include additional elements, such a controller capable of communicating with the processor **106**.

[0046] Examples of storage media include random access memory, read only memory, magnetic discs, optical discs, flash memory, virtual memory, and non-virtual memory, magnetic sets, magnetic tape, magnetic disc storage or other magnetic storage devices, or any other medium which can be used to storage the desired information and that may be accessed by an instruction execution system, as well as any combination or variation thereof, or any other type of storage medium. Likewise, the storage media may be housed locally with the processor **106**, or may be distributed in one or more servers, which may be at multiple locations and networked, such as in cloud computing applications and systems. In some implementations, the storage media can be a non-transitory storage media. In some implementations, at least a portion of the storage media may be transitory.

[0047] The communication interface **108** is configured to provide communication between the processor **106** and various other systems and devices, including to receive respiration parameter measurements **90-95** from sensors **27-32** and communicate commands and information to the hub device **68** and/or host network **76**. For example, communication interface **108** may control or include receiver/transmitters **35** that communicate with receiver/transmitter **34** on the respiration sensor device **26**. Likewise, communication interface **108** may control or include receiver/transmitter **109** that communicates with the receiver/transmitter **209***a* on the hub device **68** or receiver/transmitter **309** of the host network **76**. Likewise, communication interface **108** may receive information from wired connections, such as from the pulse oximeter **22** and/or ventilator device **40**. Likewise, communication interface **108** may communicate with or include a controller for the digital display **46**.

[0048] FIG. **5** depicts one embodiment of a method **140** of monitoring newborn infant respiration. A respiration sensor device **26** is provided at step **141**, and the respiration sensor device **26** is placed in the breathing circuit **25** at step **142**, such as between the mask **36** and breathing tube **38**. The breathing circuit is provided to the infant **2** at step **143**, such as by placing the mask over the infant's nose and mouth. One or more respiration parameters are measured by various sensors within the breathing circuit **25**, such as O_2, CO_2, flow rate, pressure, volume, temperature, and humidity. O_2 measurements **90** are measured and/or received at step **144**, such as by O_2 sensor **27**, resuscitation module **72** in the software **102** of the computing system **100**. The resuscitation module **72** then determines an FiO_2 value at step **145** based on the O_2 measurements **90**. Similarly, CO_2 measurements **91** are measured and/or received at step **146**, and an $etCO_2$ value is determined at step **147** based on the CO_2 measurements **91**. Similarly, flow measurements **92** are measured and/or received at step **148** and a tidal volume is determined at step **149** based on the flow measurements **92**. Likewise, a respiration rate may be determined at step **150** based on the flow measurements **92**, such as based on the period of the flow cycle. Alternatively or additionally, the respiration rate may be determined based on different measurements, such as based on the period of the pressure cycle. Pressure measurements **93** are measured and/or received at step **152**, and inspiratory pressure is determined at step **153** based thereon. Temperature measurements **94** are likewise measured and/or received at step **154**, and an inspiratory gas temperature (i.e. temperature of the inspiratory gas) may be determined at step **155**. For example, the inspiratory gas temperature may be the average or mean of the temperature measurements **94** recorded during the inspiratory phase of one or more breath cycles. Alternatively or additionally, an expired gas temperature is determined at step **156**, such as an average or mean of the temperature measurements **94** recorded during the expiratory phase of one or more breath cycles. Humidity measurements **95** are likewise measured and/or received at step **158**, and a humidity of an inspiratory gas is determined at step **159**. Further respiratory information **96** may be calculated at step **160**, such as comparing the inspiratory pressure and tidal volume to generate a pressure vs. volume map. Some or all of the forgoing respiratory information **96** may be displayed at step **162**, such as on the digital display **46**. At step **163**, the respiratory information **96** is stored in memory of storage system **104**. The respiratory information **96** is transmitted at step **164**, such as to the hub device **68** and/or the host network **76** as described herein. In one embodiment, steps **144** through **164** are carried out by executing instructions of the resuscitation module **72** on processor **106** of the computing system **100**. In another embodiment, one or more of the steps **144-159** are carried out within the respiration sensor device **26**, such as by executing corresponding software instructions on a processor of first computing system **100***a* therein. The respective values generated at those steps may be transmitted to the second computing system **100***b*, which may then execute steps **162** through **164**.

[0049] FIG. **6** depicts another embodiment of a method **140** of monitoring infant respiration where respiratory information trends are determined and displayed to assist a clinician in determining the respiratory condition or health status of the infant. At step **166**, stored respiratory information **96** is accessed, such as by resuscitation module **72** within computing system **100**. At step **168**, all respiration rate values are plotted with respect to time, which may include all respiration rate values determined for the infant **2** since the infant's time of birth, or may include respiration rate values over a predetermined or selected period of time. Similarly, the $etCO_2$ values are plotted with respect to time at step **169**, which may again include all values calculated since the infant's birth or a subset of those values. Likewise, tidal volume values are plotted with respect to time at step **170**, which may again include all tidal volume values calculated since the infant's birth or a subset thereof. The respiratory trend information is displayed at step **171**, which may include any or all of the respiration rate plot, the $etCO_2$ plot, and the tidal volume plot, for example.

[0050] This written description uses examples to disclose the invention, including the best mode, and also to enable any person skilled in the art to make and use the invention. Certain terms have been used for brevity, clarity and understanding. No unnecessary limitations are to be inferred therefrom beyond the requirement of the prior art because such terms are used for descriptive purposes only and are intended to be broadly construed. The patentable scope of the invention is defined by the claims, and may include other examples that occur to those skilled in the art. Such other examples are intended to be within the scope of the claims if they have features or structural elements that do not differ from the literal language of the claims, or if they include equivalent features or structural elements with insubstantial differences from the literal languages of the claims.

We claim:

1. A newborn respiration monitoring system comprising:

a flow sensor that measures a gas flow within a breathing circuit for an infant;

a CO_2 sensor that measures a CO_2 within the breathing circuit for the infant;

a resuscitation module executable on a processor of a computing system to receive the flow measurement and the CO_2 measurement and determine respiratory information for the infant; and

a digital display communicatively connected to the computing system that displays the respiratory information.

2. The newborn respiration monitoring system of claim **1**, wherein the respiratory information includes a tidal volume and an end tidal CO_2 ($etCO_2$).

3. The newborn respiration monitoring system of claim **1**, further comprising a respiration sensor device in the breathing circuit containing the CO_2 sensor and the flow sensor.

4. The newborn respiration monitoring system of claim **3**, wherein the respiration sensor device is positionable between a mask and a breathing tube of the breathing circuit.

5. The newborn respiration monitoring system of claim **4**, wherein the respiration sensor device has a first end removably connectable to the mask and a second end removably connectable to the breathing tube.

6. The newborn respiration monitoring system of claim **3**, further comprising an O_2 sensor in the respiration sensor device that measures O_2 within the breathing circuit for the infant, wherein the respiratory information determined by the resuscitation module further includes fraction of inspired oxygen (FiO_2).

7. The newborn respiration monitoring system of claim **3**, further comprising a pressure sensor in the respiration sensor device that measures pressure within the breathing circuit for the infant, wherein the respiratory information determined by the resuscitation module further includes an inspiratory pressure.

8. The newborn respiration monitoring system of claim **3**, wherein the respiration sensor device contains the processor and at least a portion of the resuscitation module.

9. The newborn respiration monitoring system of claim **8**, wherein the respiration sensor device wirelessly transmits the respiratory information to the computing system.

10. The newborn respiration monitoring system of claim **1**, further comprising at least one of an O_2 sensor that measures O_2 within the breathing circuit, a pressure sensor that measures pressure within the breathing circuit, a temperature sensor that measures temperature within the breathing circuit, and a humidity sensor that measures humidity within the breathing circuit, wherein the respiratory information determined by the resuscitation module further includes at least one of a fraction of inspired oxygen (FiO_2), an inspiratory pressure, an inspiratory gas temperature, an expired gas temperature, an inspiratory gas humidity, and a respiration rate.

11. The newborn respiration monitoring system of claim **1**, further comprising at least one of a pulse oximeter device and a co-oximeter device configured to determine at least one of an SpO_2, a SpHb, an SpMet, and an SpCO for the infant, and wherein the resuscitation module is executable to display the at least one of the SpO_2, the SpHb, the SpMet, and the SpCO on the digital display.

12. The newborn respiration monitoring system of claim **1**, wherein the resuscitation module is further executable to effect transmission of the respiratory information to at least one of a hub device or a host network.

13. The newborn respiration monitoring system of claim **1**, wherein the resuscitation module is further executable to determine one or more respiratory information trends for the infant over a period of time, and to display the one or more respiratory information trends on the digital display.

14. The newborn respiration monitoring system of claim **1**, further comprising a mask in the breathing circuit containing the CO_2 sensor and the flow sensor.

15. A method of monitoring newborn infant respiration, the method comprising:

measuring a gas flow with a flow sensor in a breathing circuit for the infant;

communicating the flow measurement to a computing system;

measuring a CO_2 with a CO_2 sensor in the breathing circuit for the infant;

communicating the CO_2 measurement to the computing system;

determining respiratory information for the infant with the computing system based on at least the flow measurement and the CO_2 measurement; and

displaying the respiratory information for the infant on a digital display communicatively connected to the computing system.

16. The method of claim **15**, wherein the wherein the respiratory information includes at least one of a tidal volume, an end tidal CO_2 ($etCO_2$), and a respiration rate.

17. The method of claim **15**, further comprising at least one of measuring an O_2 within the breathing circuit with an O_2 sensor, measuring a pressure of inspired gas within the breathing circuit with a pressure sensor, measuring a temperature within the breathing circuit with a temperature sensor, and measuring a humidity within the breathing circuit with a humidity sensor, and wherein the step of determining respiratory information further includes determining at least one of a fraction of inspired oxygen (FiO_2), an inspiratory pressure, an inspiratory gas temperature, an expired gas temperature, an inspiratory gas humidity, and a respiration rate for the infant.

18. The method of claim **17**, further comprising generating a pressure volume map for the infant based on the pressure measurement and the tidal volume.

19. The method of claim **15**, further comprising generating a respiratory information trend for the infant over a period of time and displaying the respiratory information trend on the digital display.

20. The method of claim **15**, further comprising supplying a respiration sensor device communicatively connected to the computing system, wherein the respiration sensor device contains at least the flow sensor and the CO_2 sensor and is connectable within the breathing circuit for the infant.

* * * * *

专利名称(译)	新生儿呼吸监测系统和方法		
公开(公告)号	US20170347917A1	公开(公告)日	2017-12-07
申请号	US15/174158	申请日	2016-06-06
[标]申请(专利权)人(译)	通用电气公司		
申请(专利权)人(译)	通用电气公司		
当前申请(专利权)人(译)	通用电气公司		
[标]发明人	FALK STEVEN MITCHELL STARR KAREN P PRASAD SRI RAMAPRASAD		
发明人	FALK, STEVEN MITCHELL STARR, KAREN P. PRASAD, SRI RAMAPRASAD		
IPC分类号	A61B5/087 A61B5/08 A61B5/145 A61M16/08 A61B5/00 A61M16/06 A61B5/091 A61M16/00		
CPC分类号	A61B5/087 A61M2205/3368 A61B5/742 A61B5/091 A61M16/06 A61M16/0875 A61B5/0022 A61B5/0816 A61B5/14542 A61B5/7275 A61M2230/432 A61M2016/0033 A61M2230/435 A61M2205/3331 A61B5/082 A61B5/097 A61B2503/045 A61B2505/01 A61B2560/0437 A61M16/022 A61M16/161 A61M2205/3553 A61M2205/3561 A61M2205/502 A61M2205/8206 A61M2240/00 G16H40/63 G16H50/20		
外部链接	Espacenet USPTO		

摘要(译)

新生儿呼吸监测系统包括测量气流的流量传感器和测量婴儿呼吸回路内的CO 2 的CO 2 传感器。该系统还包括可在计算系统的处理器上执行的复苏模块，以接收流量测量和CO 2 测量并确定婴儿的呼吸信息。数字显示器通信地连接到计算系统并显示呼吸信息。