No. 23-_____

In the Supreme Court of the United States

FLEUR T. TEHRANI,

Petitioner,

v.

HAMILTON TECHNOLOGIES LLC,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PATENT VOLUME

Mark Kendrick
Counsel of Record
KENDRICK INTELLECTUAL PROPERTY LAW
4127 Woodcliff Road
Sherman Oaks, CA 91403
(818) 941-8604
mkendrick852001@gmail.com

NOVEMBER 16, 2023 *COUNSEL FOR PETITIONER*
SUPREME COURT PRESS ♦ (888) 958-5705 ♦ BOSTON, MASSACHUSETTS

PATENT VOLUME TABLE OF CONTENTS

US007802571B2

(12) **United States Patent**
Tehrani

(10) **Patent No.: US 7,802,571 B2**
(45) **Date of Patent: Sep. 28, 2010**

(54) **METHOD AND APPARATUS FOR CONTROLLING A VENTILATOR**

(76) Inventor: **Fleur T. Tehrani**, 6066 E. Butterfield La., Anaheim, CA (US) 92807

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1786 days.

(21) Appl. No.: **10/935,446**

(22) Filed: **Sep. 7, 2004**

(65) **Prior Publication Data**

US 2005/0109340 A1 May 26, 2005

Related U.S. Application Data

(60) Provisional application No. 60/481,693, filed on Nov. 21, 2003.

(51) **Int. Cl.**

A61M 16/00	(2006.01)
A62B 9/00	(2006.01)
A62B 7/00	(2006.01)
F16K 31/02	(2006.01)

(52) **U.S. Cl.** **128/204.23**; 128/204.18; 128/204.21; 128/202.22; 128/205.23; 128/205.11

(58) **Field of Classification Search** 128/204.18, 128/204.21, 204.23, 716, 719, 202.22, 205.23, 128/205.11

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,414,747	A	1/1947	Kirschbaum
3,734,091	A	5/1973	Taplin
4,121,578	A	10/1978	Torzala
4,326,513	A	4/1982	Schulz
4,448,192	A	5/1984	Stawitcke et al.
4,584,996	A	4/1986	Blum
4,665,911	A	5/1987	Williams et al.

(Continued)

FOREIGN PATENT DOCUMENTS

DE	4309923	A1	9/1994

(Continued)

OTHER PUBLICATIONS

G. A. Saxton, Jr., and G. H. Myers, "A servomechanism for automatic regulation of pulmonary ventilation," *Journal of Applied Physiology*, vol. 11, pp. 326-328, 1957.

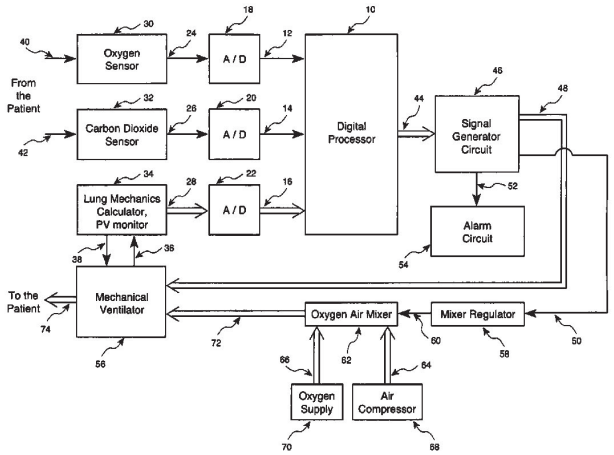
(Continued)

Primary Examiner—Tatyana Zalukaeva
Assistant Examiner—Nihir Patel
(74) *Attorney, Agent, or Firm*—Sean D. Burdick

(57) **ABSTRACT**

Method and apparatus for controlling a ventilator are described. The invention can be used to control mechanical ventilators as well as respiratory assist devices such as CPAP machines. The apparatus receives input data indicative of patient's oxygen level. A controller determines PEEP, or CPAP, and F_{IO2}, on the basis of data indicative of the patient's oxygen level. In an alternative embodiment, the apparatus further receives input data indicative of patient's carbon dioxide levels, respiratory elastance and airway resistance, and barometric pressure. The controller further utilizes the said input data to determine the optimal values of tidal volume and breathing frequency for a next breath of the patient, and uses the respiratory elastance and airway resistance data to determine any necessary adjustments in the I:E ratio. The controller also applies safety rules, detects and corrects artifacts, and generates warning signals when needed.

45 Claims, 14 Drawing Sheets



U.S. PATENT DOCUMENTS

4,773,411	A		9/1988	Downs	
4,889,116	A		12/1989	Taube	
4,986,268	A		1/1991	Tehrani	
5,103,814	A		4/1992	Maher	
5,315,990	A		5/1994	Mondry	
5,365,922	A	*	11/1994	Raemer	128/204.23
5,388,575	A	*	2/1995	Taube	128/204.23
5,402,796	A		4/1995	Packer et al.	
5,558,086	A		9/1996	Smith et al.	
5,575,283	A		11/1996	Sjoestrand	
5,617,846	A		4/1997	Graetz et al.	
5,682,877	A		11/1997	Mondry	
5,692,497	A		12/1997	Schnitzer et al.	
5,705,735	A	*	1/1998	Acorn	73/23.3
5,738,090	A		4/1998	Lachmann et al.	
5,752,509	A		5/1998	Lachmann et al.	
5,937,854	A		8/1999	Stenzler	
6,105,575	A		8/2000	Estes et al.	
6,116,241	A		9/2000	Huygen et al.	
6,148,814	A		11/2000	Clemmer et al.	
6,158,432	A		12/2000	Biondi et al.	
6,305,374	B1		10/2001	Zdrojkowski et al.	
6,355,002	B1		3/2002	Faram et al.	
6,371,114	B1		4/2002	Schmidt et al.	
6,390,091	B1		5/2002	Banner et al.	
6,512,938	B2		1/2003	Claure et al.	
6,532,958	B1		3/2003	Buan et al.	
6,539,940	B2		4/2003	Zdrojkowski et al.	
6,561,187	B2		5/2003	Schmidt et al.	
6,578,575	B1		6/2003	Jonson	
6,655,382	B1		12/2003	Kolobow	
6,663,574	B2		12/2003	Faram et al.	
6,668,829	B2		12/2003	Biondi et al.	
6,671,529	B2		12/2003	Claure et al.	
6,752,151	B2		6/2004	Hill	
6,796,305	B1		9/2004	Banner et al.	
7,210,478	B2		5/2007	Banner	
2002/0110849	A1		8/2002	Leonhardt et al.	
2003/0060725	A1		3/2003	Kline	
2003/0111078	A1		6/2003	Habashi	
2003/0145852	A1		8/2003	Schmidt et al.	
2004/0003813	A1	*	1/2004	Banner et al.	128/204.21
2005/0051168	A1	*	3/2005	DeVries et al.	128/204.21
2007/0000494	A1		1/2007	Banner	

FOREIGN PATENT DOCUMENTS

EP	0 099283	A1	6/1983
EP	0658331	A1	6/1995
EP	0303502		12/1998
GB	835192		5/1960
WO	99/04841		2/1999
WO	99/61088		12/1999

OTHER PUBLICATIONS

M. J. Frumin, N. A. Bergman, and D. A. Holaday, "Carbon dioxide and oxygen blood levels with a carbon dioxide controlled artificial respirator," *Anesthesiology*, vol. 20(3), pp. 313-321, 1959.

Y. Mitamura, T. Mikami, H. Sugawara, and C. Yoshimoto, "An optimally controlled respirator," *IEEE Transactions on Biomedical Engineering*, BME-18, pp. 330-337, 1971.

J. R. Coles, W. A. Brown, and D. G. Lampard, "Computer control of ventilation and anesthesia," *Medical and Biological Engineering*, vol. 11, pp. 262-267, 1973.

Y. Mitamura, T. Mikami, K. Yamamoto, and K. Mimura, "A dual control system for assisting respiration," *Medical and Biological Engineering*, vol. 13(6), pp. 846-854, 1975.

A. M. Hewlett, A. S. Platt, V. G. Terry, "Mandatory minute volume," *Anaesthesia*, vol. 32, pp. 163-169, 1977.

R. L. Coon, E. J. Zuperku, and J. P. Kampine, "Systemic arterial blood pH servo control of mechanical ventilation," *Anesthesiology*, vol. 49(3), pp. 201-204, 1978.

K. B. Ohlson, D. R. Westenskow, and W. S. Jordan, "A microprocessor based feedback controller for mechanical ventilation," *Annals of Biomedical Engineering*, vol. 10, pp. 35-48, 1982.

W. F. Fincham, and F. T. Tehrani, "A mathematical model of the human respiratory system," *Journal of Biomedical Engineering*, vol. 5, pp. 125-133, 1983.

F. W. Chapman, J. C. Newell, and R. J. Roy, "A feedback controller for ventilatory therapy," *Annals of Biomedical Engineering*, vol. 13, pp. 359-372, 1985.

M. H. Giard, F. O. Bertrand, D. Robert, and J. Pernier, "An algorithm for automatic control of O_2 and CO_2 in artificial ventilation," *IEEE Transactions on Biomedical Engineering*, vol. BME-32, No. 9, pp. 658-667, 1985.

T. D. East, K. P. Adriano, N. L. Pace, "Computer-controlled optimization of positive end-expiratory pressure," *Critical Care Medicine*, vol. 14, No. 9, pp. 792-797, 1986.

R. G. Ritchie, E. A. Ernst, B. L. Pate, J. P. Pearson, and L. C. Sheppard, "Closed-loop control of an anesthesia delivery system: Development and animal testing," *IEEE Transactions on Biomedical Engineering*, BME-34(6), pp. 437-443, 1987.

T. D. East, J. C. C. M. Veen, T. A. Jonker, N. L. Pace, and S. McJames, "Computer-controlled positive end-expiratory pressure titration for effective oxygenation without frequent blood gases." *Critical Care Medicine*, vol. 16(3), pp. 252-257, 1988.

R. Rudowski, L. Skreta, S. Baehrendtz, A. Bokliden, and G. Matell, "Lung function analysis and optimization during artificial ventilation. A personal computer-based system." *Computer Methods and Programs in Biomedicine*, vol. 31, pp. 33-42, 1990.

R. G. Ritchie, E. A. Ernst, B. L. Pate, J. P. Pearson, and L. C. Sheppard, "Automatic control of anesthetic delivery and ventilation during surgery," *Medical Progress through Technology*, vol. 16, pp. 61-67, 1990.

R. Rudowski, A. Bokliden, A. Carstensen, H. Gill, U. Ludwigs, G. Matell, "Multivariable optimization of mechanical ventilation. A linear programming approach." *International Journal of Clinical Monitoring and Computing*. vol. 8, pp. 107-115, 1991.

T. D. East, C. R. Tolle, S. McJames, R. M. Farrell, J. X. Brunner, "A non-linear closed-loop controller for oxygenation based on a clinically proven fifth dimensional quality surface," *Anesthesiology*, vol. 75, A468, 1991.

M. Dojat, L. Brochard, F. Lemaire, and A. Harf, "A knowledge-based system for assisted ventilation of patients in intensive care units," *International Journal of Clinical Monitoring and Computing*, vol. 9, pp. 239-250, 1992.

F. T. Tehrani, "Mathematical analysis and computer simulation of the respiratory system in the newborn infant," *IEEE Transactions on Biomedical Engineering*, vol. 40, No. 5, pp. 475-481, 1993.

T. P. Laubscher, W. Heinrichs, N. Weiler, G. Hartmann, and J. X. Brunner, "An adaptive lung ventilation controller," *IEEE Transactions on Biomedical Engineering*, vol. 41(1), pp. 51-59, 1994.

T. L. Fernando, J. S. Packer, and J. F. Cade, "A closed-loop system for controlling blood oxygen and carbon dioxide levels in mechanically ventilated patients," *Control Eng. Practice*, vol. 3, No. 10, pp. 1433-1440, 1995.

J. Schaublin, M. Derighetti, P. Feigenwinter, S. Petersen-Felix, and A. M. Zbinden, "Fuzzy logic control of mechanical ventilation during anesthesia," *British Journal of Anesthesiology*, vol. 77, pp. 636-641, 1996.

M. Dojat, F. Pachet, Z. Guessoum, D. Touchard, A. Harf, L. Brochard, "NeoGanesh: a working system for the automated control of assisted ventilation in ICUs," *Artificial Intelligence in Medicine*, vol. 11, pp. 97-117, 1997.

T. Fernando, J. Cade, and J. Packer, "Automatic control of arterial carbon dioxide tension in mechanically ventilated patients," *IEEE Transactions on Information Technology in Biomedicine*, vol. 6(4), pp. 269-276, 2002.

T. Lo, F. T. Tehrani, M. Rogers, M. Lum, T. Malinowski, S. Afuwape, M. Terry, B. Grundl, "A dual closed-loop controller for mechanical ventilation," (abstract), *American Journal of Respiratory and Critical Care Medicine*, vol. 165(8), supplement, part 2, Apr. 2002.

A. B. Otis, W. O. Fenn, and H. Rahn, "Mechanics of breathing in man," *Journal of Applied Physiology*, vol. 2, pp. 592-607, 1950.

I. R. Beddis, P. Collins, N. M. Levy, S. Godfrey, and M. Silverman, "New technique for servo-control of arterial oxygen tension in preterm infants," *Archives of Disease in Childhood*, vol. 54, pp. 278-280, 1979.

A. Sano, and M. Kikucki, "Adaptive control of arterial oxygen pressure of newborn infants under incubator oxygen treatments," *Proceedings of IEE*, vol. 132(Pt. D., No. 5), pp. 205-211, 1985.

C. Yu, W. G. He, J. M. So, R. Roy, H. Kaufman, and J. C. Newell, "Improvement in arterial oxygen control using multiple model adaptive control procedures," *IEEE Transactions on Biomedical Engineering*, BME-34(8), pp. 567-574, 1987.

R. E. Dugdale, R. G. Cameron, and G. T. Lealman, "Closed-loop control of the partial pressure of arterial oxygen in neonates," *Clinical Physics and Physiological Measurement*, vol. 9(4), pp. 291-305, 1988.

A. H. Morris, C. J. Wallace, T. P. Clemmer, J. F. Orme Jr., L. K. Weaver, N. C. Dean, S. Butler, M. R. Suchyta, T. D. East, D. F. Sittig, "Extracorporeal CO_2 removal therapy for adult respiratory distress syndrome patients: a computerized protocol controlled trial," *Râeanimation, soins intensifs, mâedecine d'urgence*, vol. 6(7), pp. 485-490, 1990.

D. F. Sittig, R. M. Gardner, A. H. Morris, and C. J. Wallace, "Clinical evaluation of computer-based respiratory care algorithms," *International Journal of Clinical Monitoring and Computing*, vol. 7, pp. 177-185, 1990.

P. E. Morozoff, and R. W. Evans, "Closed loop control of S_{aO2} in the neonate," *Biomedical Instrumentation and Technology*, vol. 26, pp. 117-123, 1992.

F. T. Tehrani, "A microcomputer oxygen control system for ventilatory therapy," *Annals of Biomedical Engineering*, vol. 20(5), pp. 547-558, 1992.

J. R. Anderson, T. D. East, J. Coombs, T. Clemmer, J. Orme, L. Weaver, "Clinical trial of a non-linear closed-loop controller for oxygenation during ARDS," *Critical Care Medicine*, vol. 22, A188, Jan. 1994.

F. T. Tehrani, and A. R. Bazar, "A feedback controller for supplemental oxygen treatment of newborn infants: a simulation study," *Medical Engineering and Physics*, vol. 16, pp. 329-333, 1994.

A. Rossi, G. Polese, G. Brandi, G. Conti, Intrinsic positive end-expiratory pressure (PEEPi), *Intensive Care Medicine*, vol. 21, pp. 522-536, 1995.

D. B. Waisel, J. C. Fackler, J. X. Brunner, I. Kohane, "PEFIOS: An expert closed-loop oxygenation algorithm," *MEDINFO 95*, Proceedings of the 8th World Congress, pp. 1132-1136, 1995.

G. A. Lotti, J. X. Brunner, A. Braschi, T. Laubscher, M. C. Olivei, A. Palo, C. Galbusera, A. Comelli, "Closed-loop control of airway occlusion pressure at 0.1 second ($P_{0.1}$) applied to pressure-support ventilation: Algorithm and application in intubated patients," *Critical Care Medicine*, vol. 24(5), pp. 771-779, 1996.

D. B. Raemer, X. Ji, and G. P. Topulos, "F_{IX} controller: an instrument to automatically adjust inspired oxygen fraction using feedback control from a pulse oximeter," *Journal of Clinical Monitoring*, vol. 13, pp. 91-101, 1997.

F. T. Tehrani, "A control system for oxygen therapy of premature infants," in *The Proceedings of the 23rd Annual International Conference of IEEE Engineering in Medicine and Biology Society*, vol. 23(2), pp. 2059-2062, Oct. 2001.

F. T. Tehrani, M. Rogers, T. Lo, T. Malinowski, S. Afuwape, M. Lum, B. Grundl, and M. Terry, "Closed-loop control of the inspired fraction of oxygen in mechanical ventilation," *Journal of Clinical Monitoring and Computing*, vol. 17(6), pp. 367-376, 2002.

P. Saura, L. Blanch, "How to set positive end-expiratory pressure," *Respiratory Care*, vol. 47 (3), pp. 279-295, 2002.

J.M. Halter et al, "Positive End-Expiratory Pressure after a Recruitment Maneuver Prevents Both Alveolar Collapse and Recruitment/Decrectuitment," 2003, *American Journal of Respiratory and Critical Care Medicine*, 167:1620-1626.

S.E. Lapinsky et al., "Safety and efficacy of a sustained inflation for alveolar recruitment in adults with respiratory failure," 1999, *Intensive Care Medicine*, 25:1297-1301.

R.G. Brower et al., "Effects of recruitment maneuvers in patients with acute lung injury and acute respiratory distress syndrome ventilated with high positive end-expiratory pressure," 2003, *Critical Care Medicine*, 31(11):2592-2597.

* cited by examiner

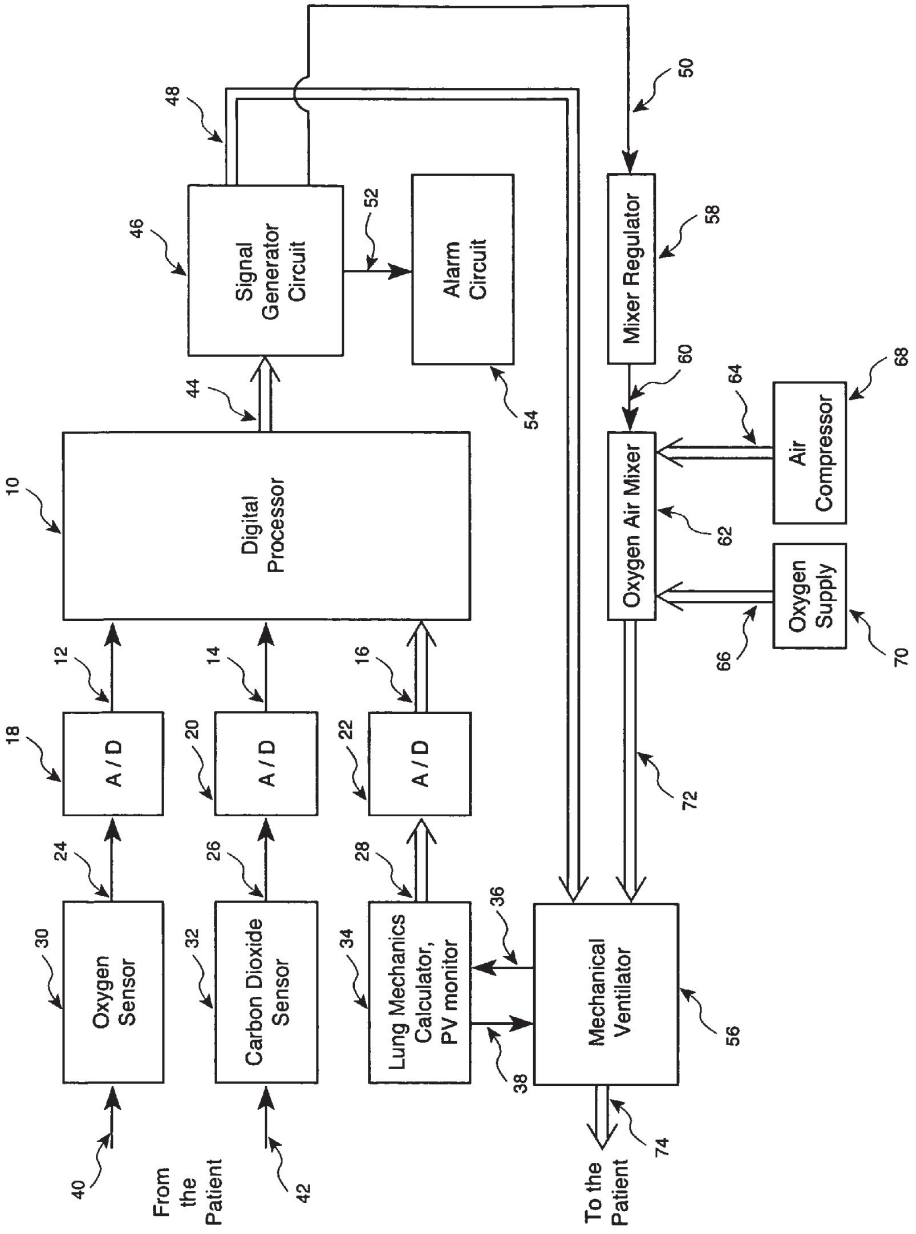

Digital Processor
10
Signal Generator Circuit
46
48
Alarm Circuit
52
54
Mixer Regulator
58
50
44
60
Oxygen Air Mixer
62
64
Air Compressor
68
Oxygen Supply
66
70
12
14
16
A / D
18
20
22
24
26
28
Oxygen Sensor
30
Carbon Dioxide Sensor
32
Lung Mechanics Calculator, PV monitor
34
36
38
Mechanical Ventilator
56
72
40
From the Patient
42
To the Patient
74

Figure 1

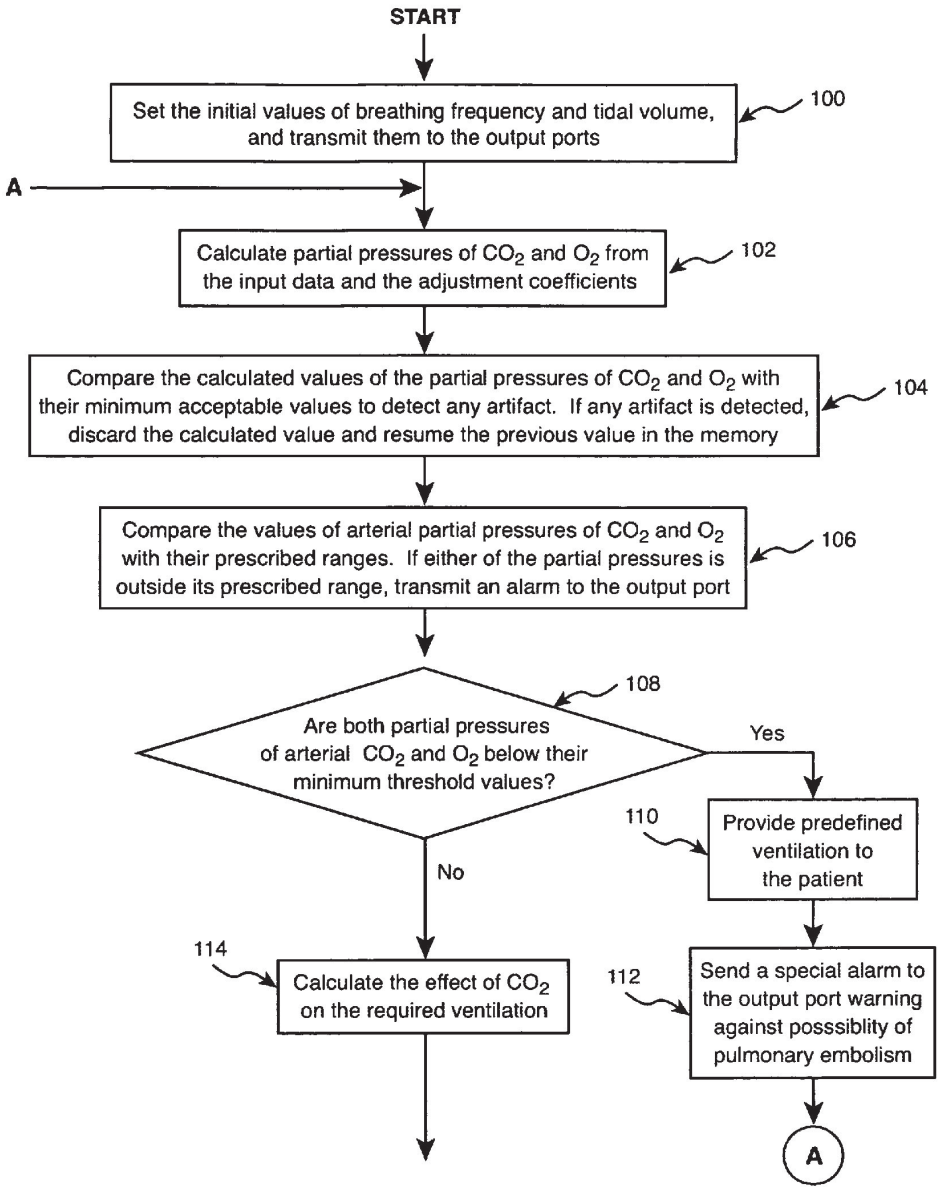

START
Set the initial values of breathing frequency and tidal volume, and transmit them to the output ports
100
A
Calculate partial pressures of CO_2 and O_2 from the input data and the adjustment coefficients
102
Compare the calculated values of the partial pressures of CO_2 and O_2 with their minimum acceptable values to detect any artifact. If any artifact is detected, discard the calculated value and resume the previous value in the memory
104
Compare the values of arterial partial pressures of CO_2 and O_2 with their prescribed ranges. If either of the partial pressures is outside its prescribed range, transmit an alarm to the output port
106
Are both partial pressures of arterial CO_2 and O_2 below their minimum threshold values?
108
Yes
No
Provide predefined ventilation to the patient
110
Send a special alarm to the output port warning against posssiblity of pulmonary embolism
112
Calculate the effect of CO_2 on the required ventilation
114
A

Figure 2a

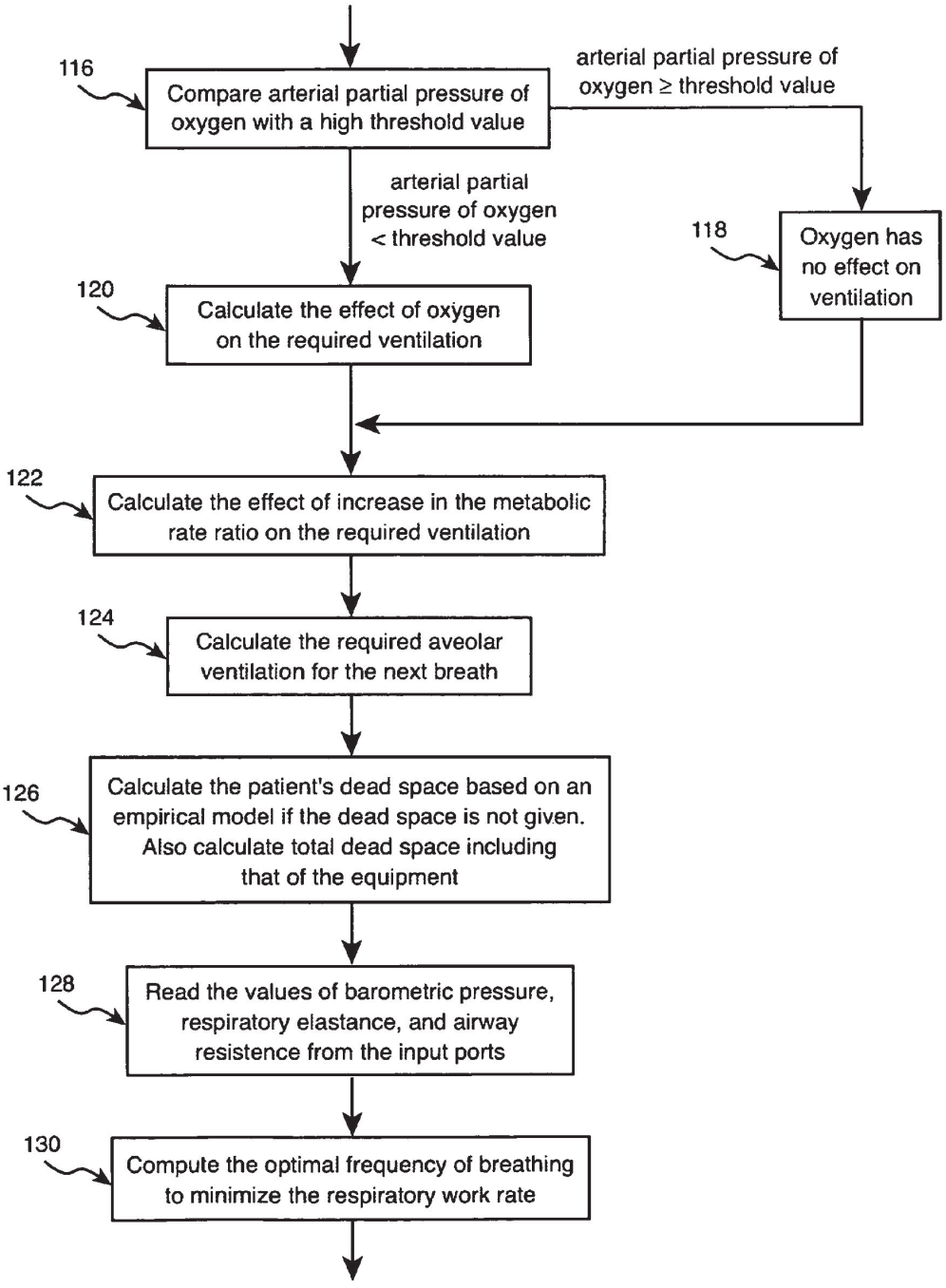

116
Compare arterial partial pressure of oxygen with a high threshold value
arterial partial pressure of oxygen ≥ threshold value
arterial partial pressure of oxygen < threshold value
118
Oxygen has no effect on ventilation
120
Calculate the effect of oxygen on the required ventilation
122
Calculate the effect of increase in the metabolic rate ratio on the required ventilation
124
Calculate the required aveolar ventilation for the next breath
126
Calculate the patient's dead space based on an empirical model if the dead space is not given. Also calculate total dead space including that of the equipment
128
Read the values of barometric pressure, respiratory elastance, and airway resistence from the input ports
130
Compute the optimal frequency of breathing to minimize the respiratory work rate

Figure 2b

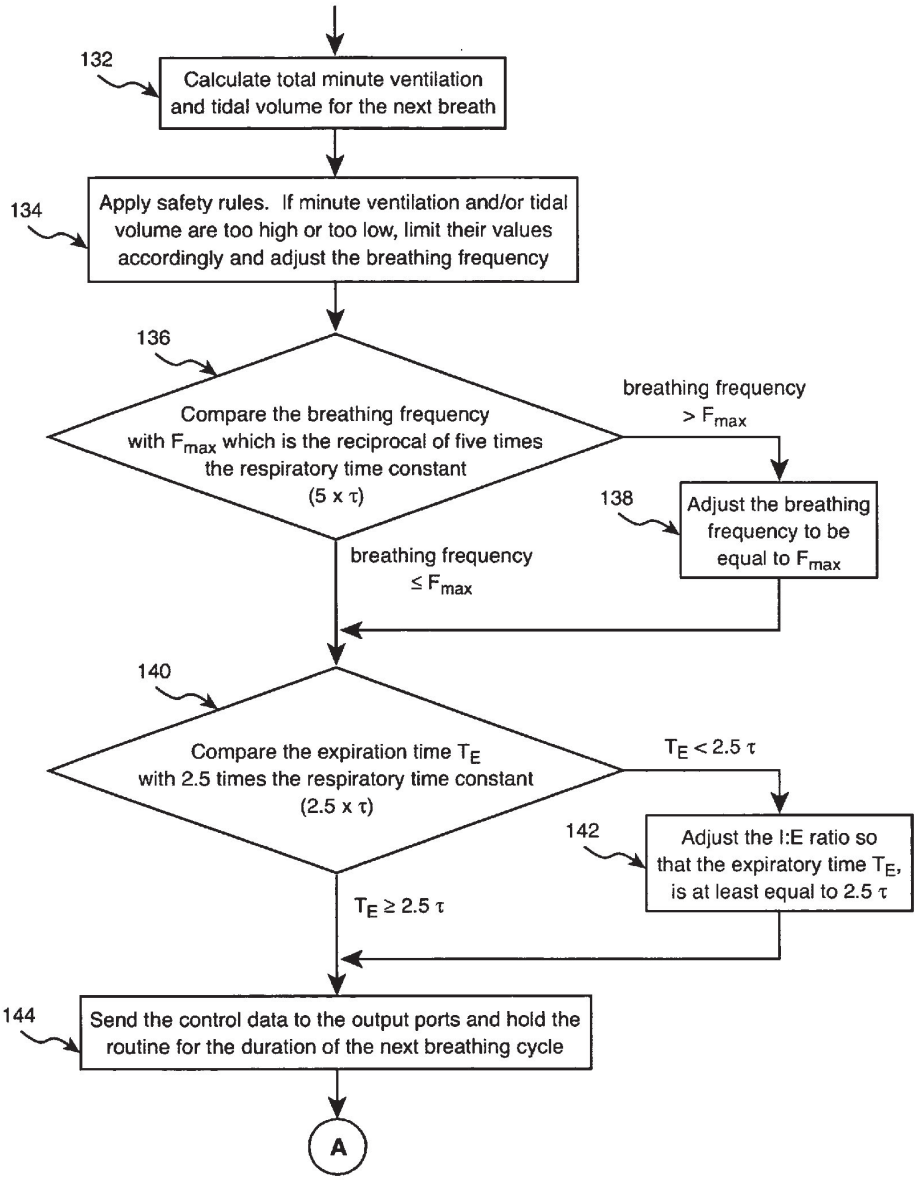

132
Calculate total minute ventilation and tidal volume for the next breath
134
Apply safety rules. If minute ventilation and/or tidal volume are too high or too low, limit their values accordingly and adjust the breathing frequency
136
Compare the breathing frequency with F_{max} which is the reciprocal of five times the respiratory time constant (5 x τ)
breathing frequency > F_{max}
138
Adjust the breathing frequency to be equal to F_{max}
breathing frequency ≤ F_{max}
140
Compare the expiration time T_E with 2.5 times the respiratory time constant (2.5 x τ)
$T_E < 2.5\ \tau$
142
Adjust the I:E ratio so that the expiratory time T_E, is at least equal to 2.5 τ
$T_E \geq 2.5\ \tau$
144
Send the control data to the output ports and hold the routine for the duration of the next breathing cycle
A

Figure 2c

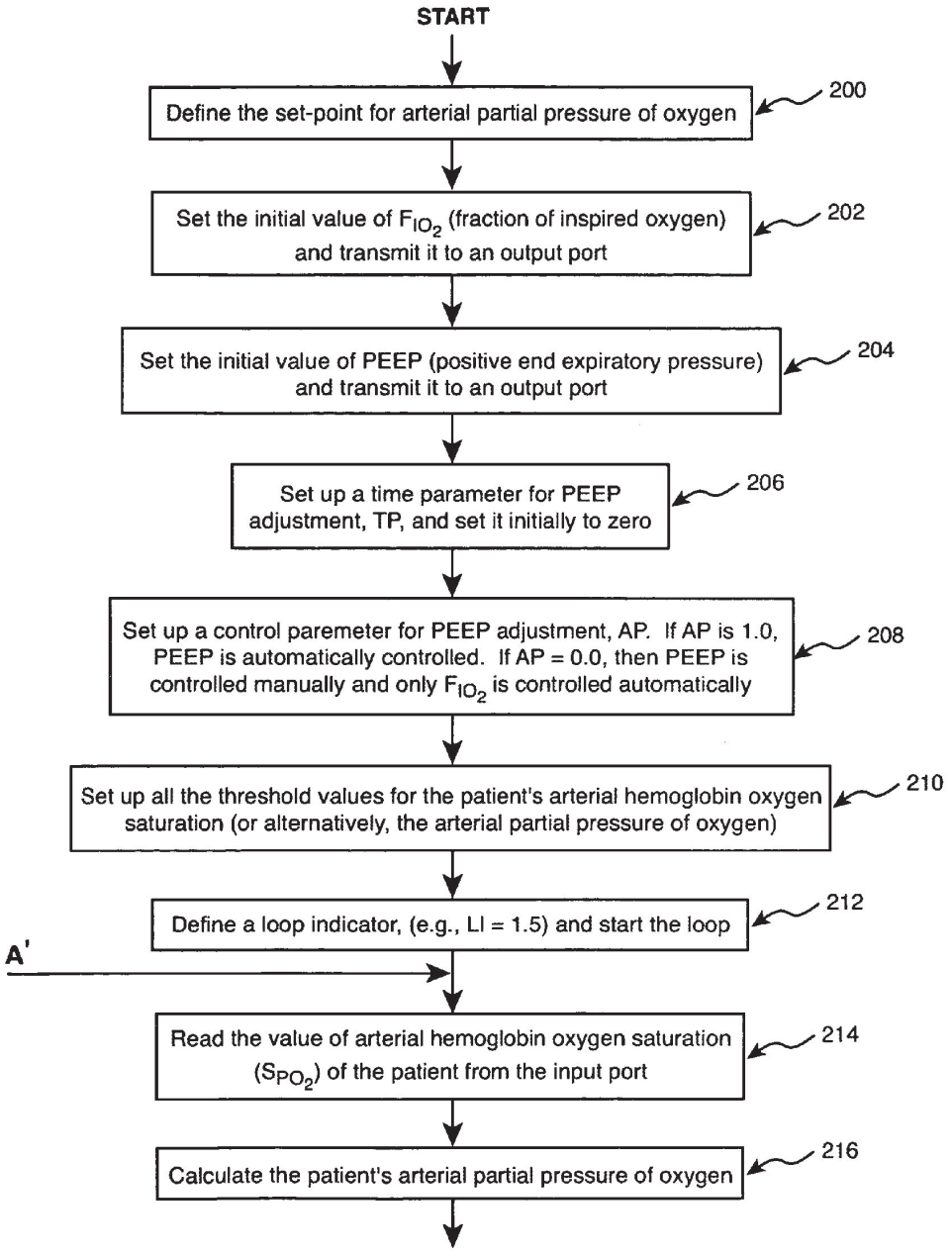

START
Define the set-point for arterial partial pressure of oxygen
200
Set the initial value of F_{IO_2} (fraction of inspired oxygen) and transmit it to an output port
202
Set the initial value of PEEP (positive end expiratory pressure) and transmit it to an output port
204
Set up a time parameter for PEEP adjustment, TP, and set it initially to zero
206
Set up a control paremeter for PEEP adjustment, AP. If AP is 1.0, PEEP is automatically controlled. If AP = 0.0, then PEEP is controlled manually and only F_{IO_2} is controlled automatically
208
Set up all the threshold values for the patient's arterial hemoglobin oxygen saturation (or alternatively, the arterial partial pressure of oxygen)
210
Define a loop indicator, (e.g., LI = 1.5) and start the loop
212
A'
Read the value of arterial hemoglobin oxygen saturation (S_{PO_2}) of the patient from the input port
214
Calculate the patient's arterial partial pressure of oxygen
216

Figure 3a

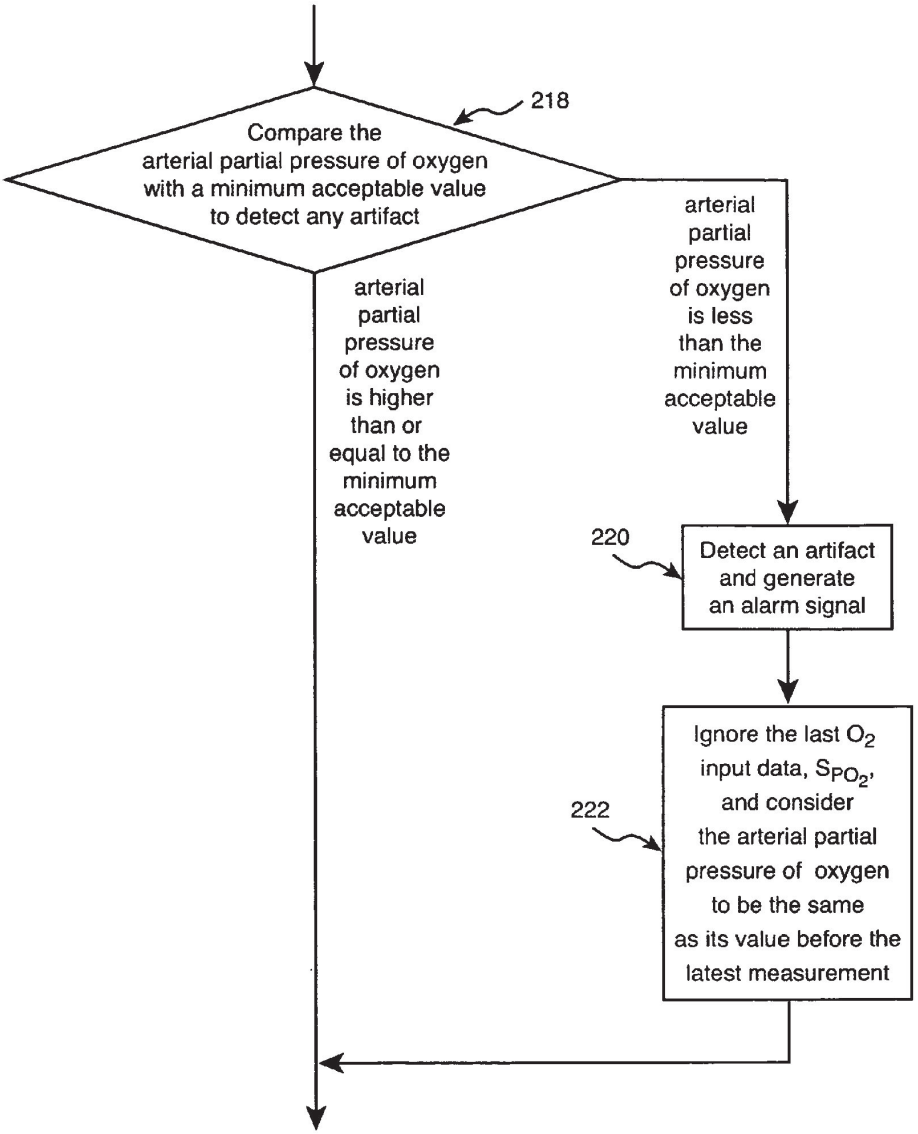

218
Compare the arterial partial pressure of oxygen with a minimum acceptable value to detect any artifact
arterial partial pressure of oxygen is higher than or equal to the minimum acceptable value
arterial partial pressure of oxygen is less than the minimum acceptable value
220
Detect an artifact and generate an alarm signal
222
Ignore the last O_2 input data, S_{PO_2}, and consider the arterial partial pressure of oxygen to be the same as its value before the latest measurement

Figure 3b

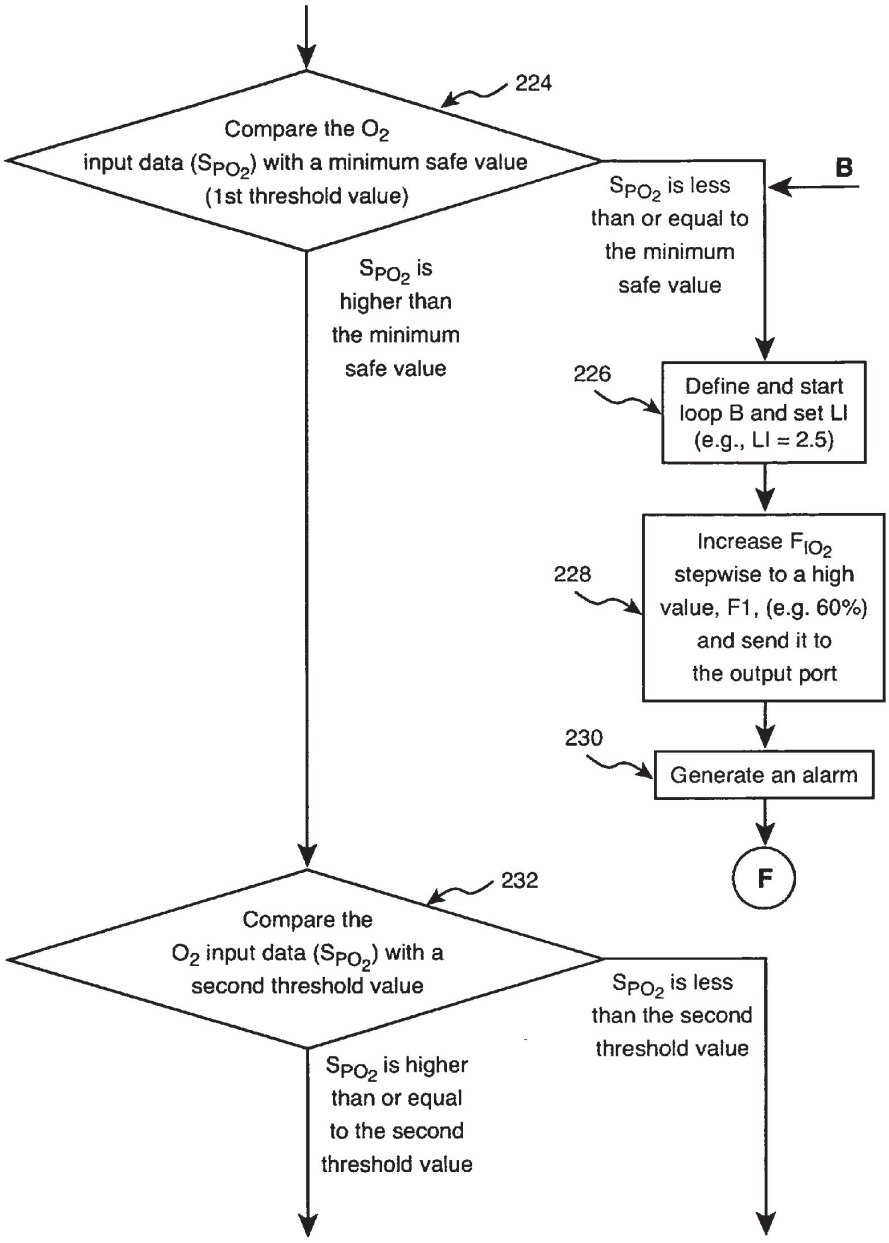

224
Compare the O_2 input data (S_{PO_2}) with a minimum safe value (1st threshold value)
S_{PO_2} is less than or equal to the minimum safe value
B
S_{PO_2} is higher than the minimum safe value
226
Define and start loop B and set LI (e.g., LI = 2.5)
228
Increase F_{IO_2} stepwise to a high value, F1, (e.g. 60%) and send it to the output port
230
Generate an alarm
F
232
Compare the O_2 input data (S_{PO_2}) with a second threshold value
S_{PO_2} is less than the second threshold value
S_{PO_2} is higher than or equal to the second threshold value

Figure 3c

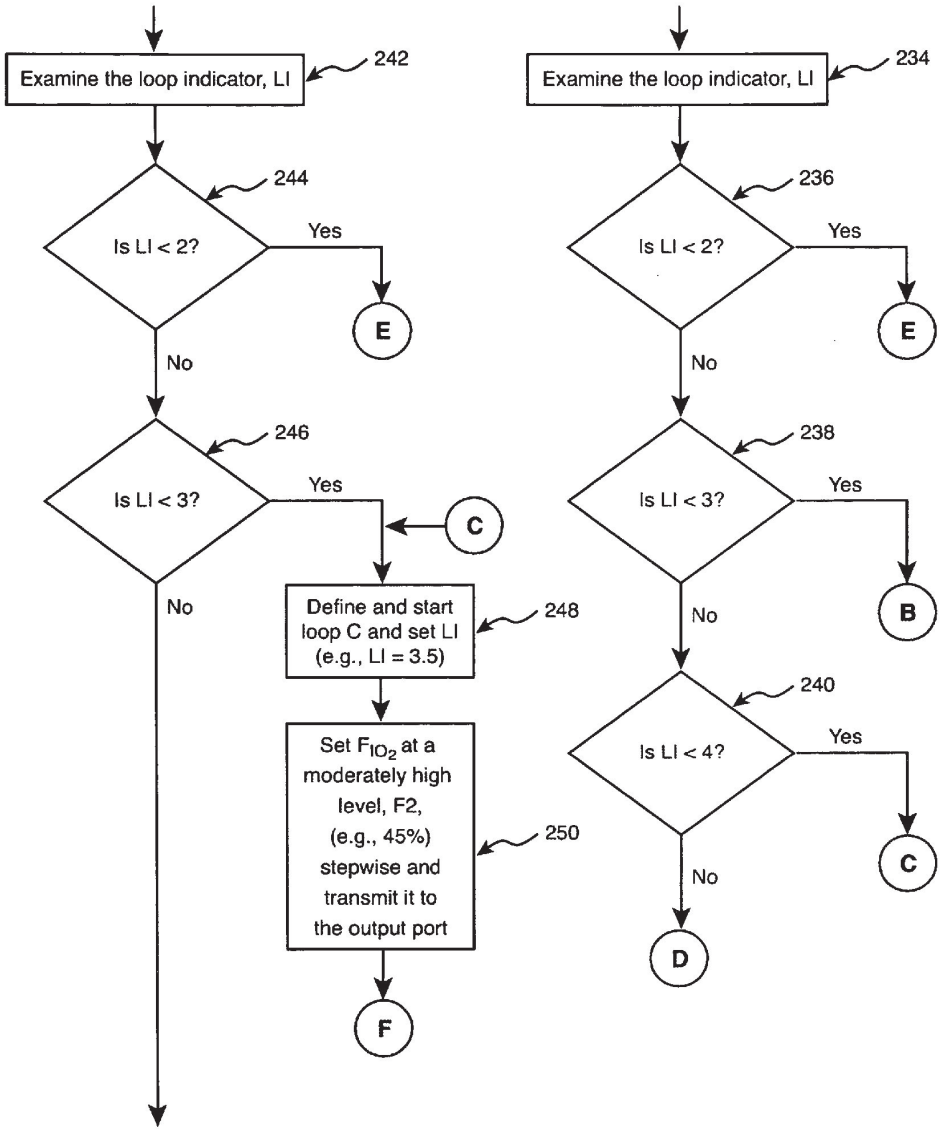

Examine the loop indicator, LI
242
Is LI < 2?
244
Yes
E
No
Is LI < 3?
246
Yes
C
No
Define and start loop C and set LI (e.g., LI = 3.5)
248
Set F_{IO_2} at a moderately high level, F2, (e.g., 45%) stepwise and transmit it to the output port
250
F
Examine the loop indicator, LI
234
Is LI < 2?
236
Yes
E
No
Is LI < 3?
238
Yes
B
No
Is LI < 4?
240
Yes
C
No
D

Figure 3d

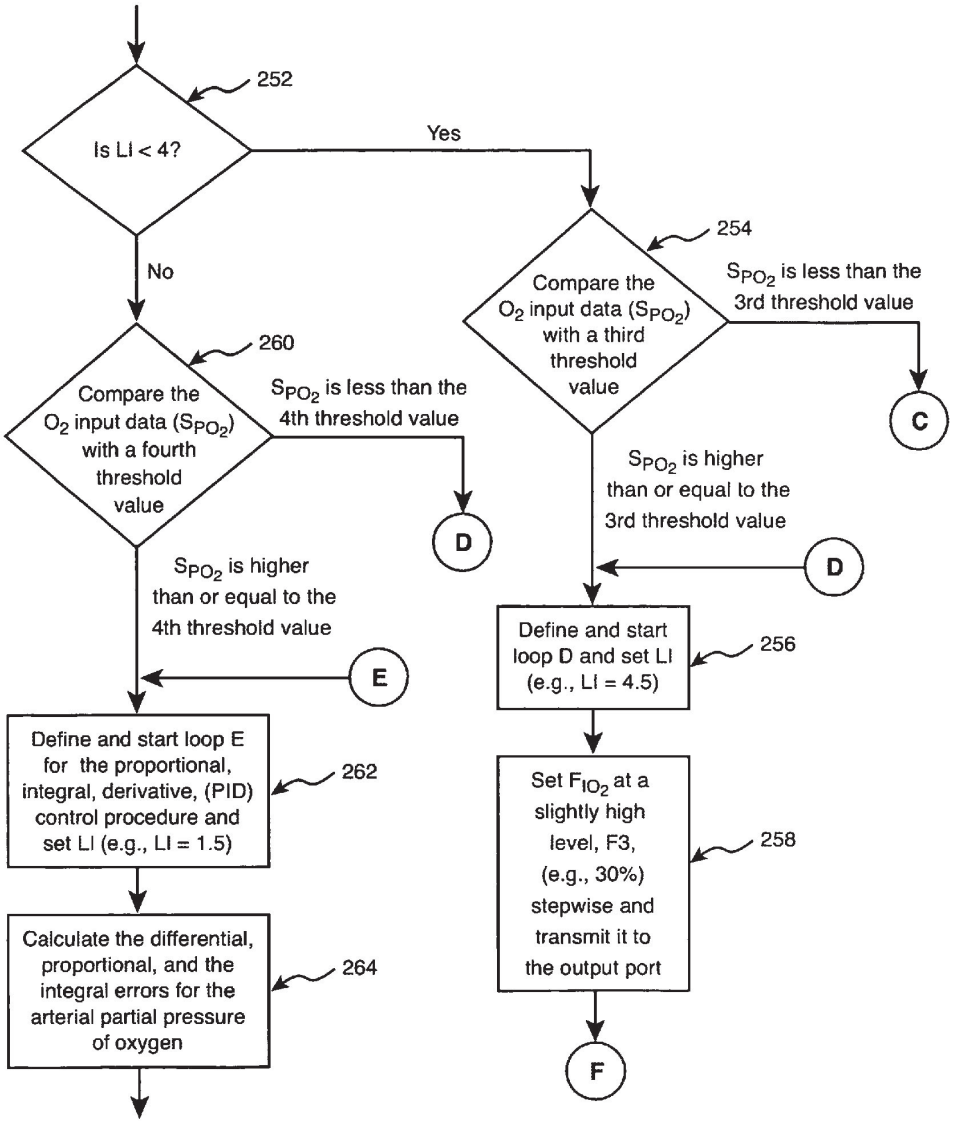

252
Is LI < 4?
Yes
No
254
Compare the O_2 input data (S_{PO_2}) with a third threshold value
S_{PO_2} is less than the 3rd threshold value
C
S_{PO_2} is higher than or equal to the 3rd threshold value
D
260
Compare the O_2 input data (S_{PO_2}) with a fourth threshold value
S_{PO_2} is less than the 4th threshold value
D
S_{PO_2} is higher than or equal to the 4th threshold value
E
Define and start loop D and set LI (e.g., LI = 4.5)
256
Set F_{IO_2} at a slightly high level, F3, (e.g., 30%) stepwise and transmit it to the output port
258
F
Define and start loop E for the proportional, integral, derivative, (PID) control procedure and set LI (e.g., LI = 1.5)
262
Calculate the differential, proportional, and the integral errors for the arterial partial pressure of oxygen
264

Figure 3e

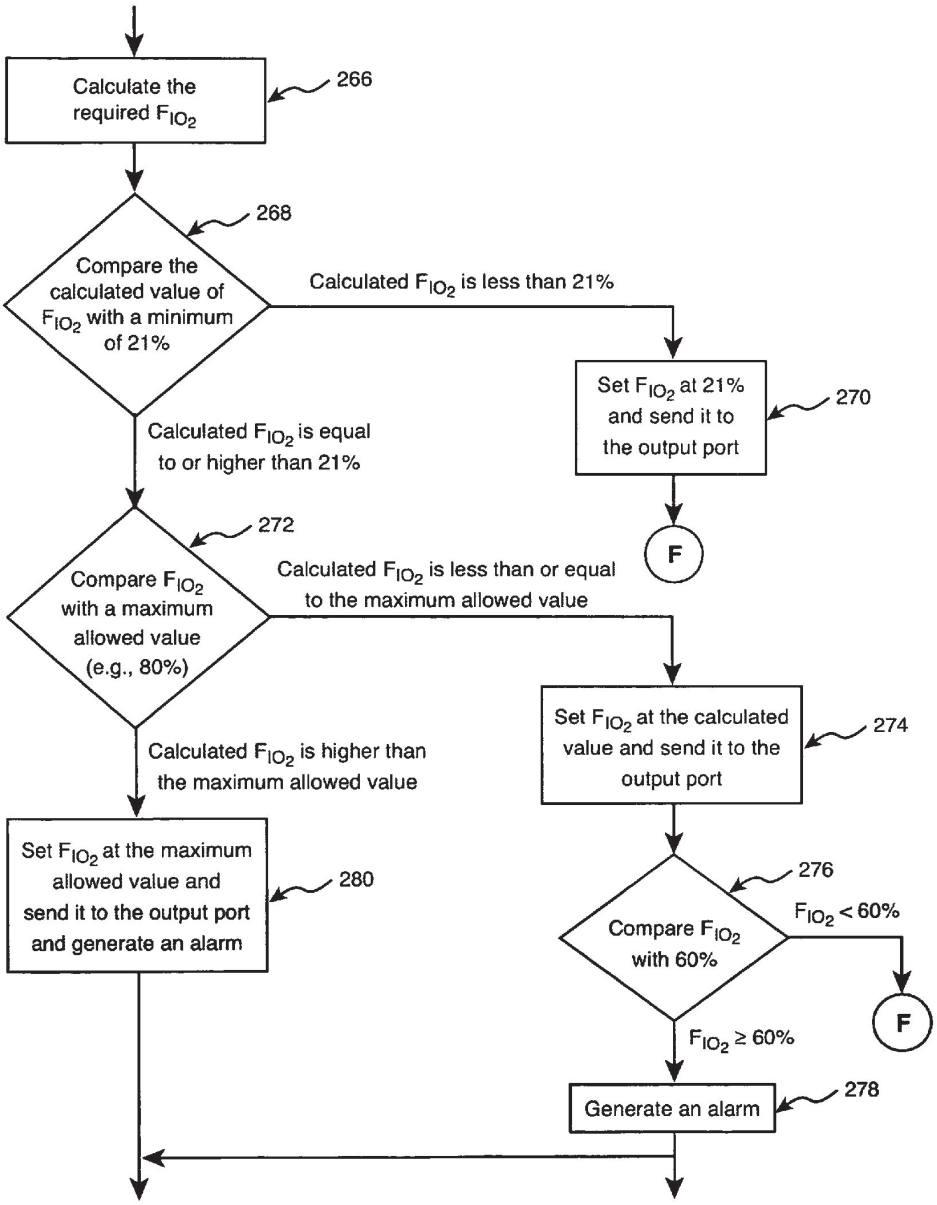

Calculate the required F_{IO_2}
266
Compare the calculated value of F_{IO_2} with a minimum of 21%
268
Calculated F_{IO_2} is less than 21%
Set F_{IO_2} at 21% and send it to the output port
270
F
Calculated F_{IO_2} is equal to or higher than 21%
Compare F_{IO_2} with a maximum allowed value (e.g., 80%)
272
Calculated F_{IO_2} is less than or equal to the maximum allowed value
Set F_{IO_2} at the calculated value and send it to the output port
274
Calculated F_{IO_2} is higher than the maximum allowed value
Set F_{IO_2} at the maximum allowed value and send it to the output port and generate an alarm
280
Compare F_{IO_2} with 60%
276
$F_{IO_2} < 60\%$
F
$F_{IO_2} \geq 60\%$
Generate an alarm
278

Figure 3f

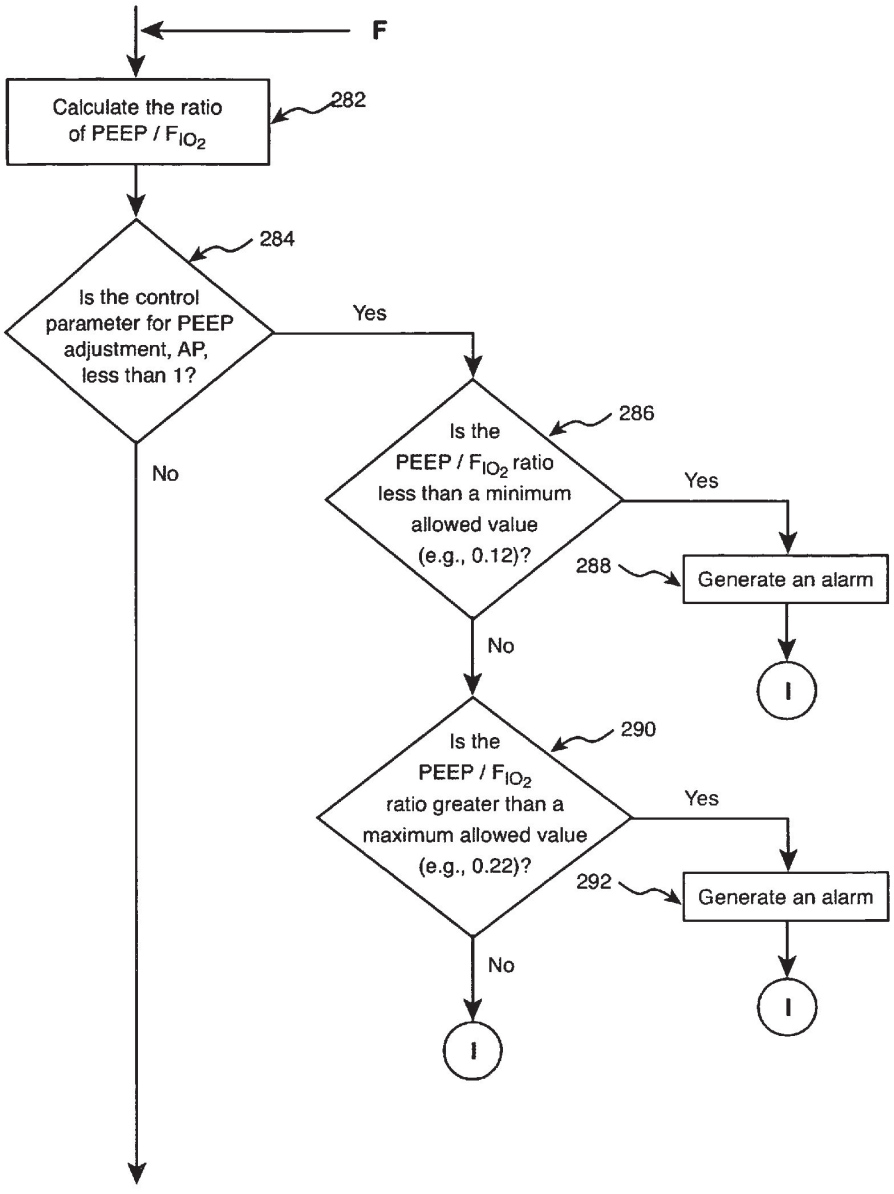

F
Calculate the ratio of PEEP / F_{IO_2}
282
284
Is the control parameter for PEEP adjustment, AP, less than 1?
Yes
No
286
Is the PEEP / F_{IO_2} ratio less than a minimum allowed value (e.g., 0.12)?
Yes
288
Generate an alarm
No
290
Is the PEEP / F_{IO_2} ratio greater than a maximum allowed value (e.g., 0.22)?
Yes
292
Generate an alarm
No
I
I
I

Figure 3g

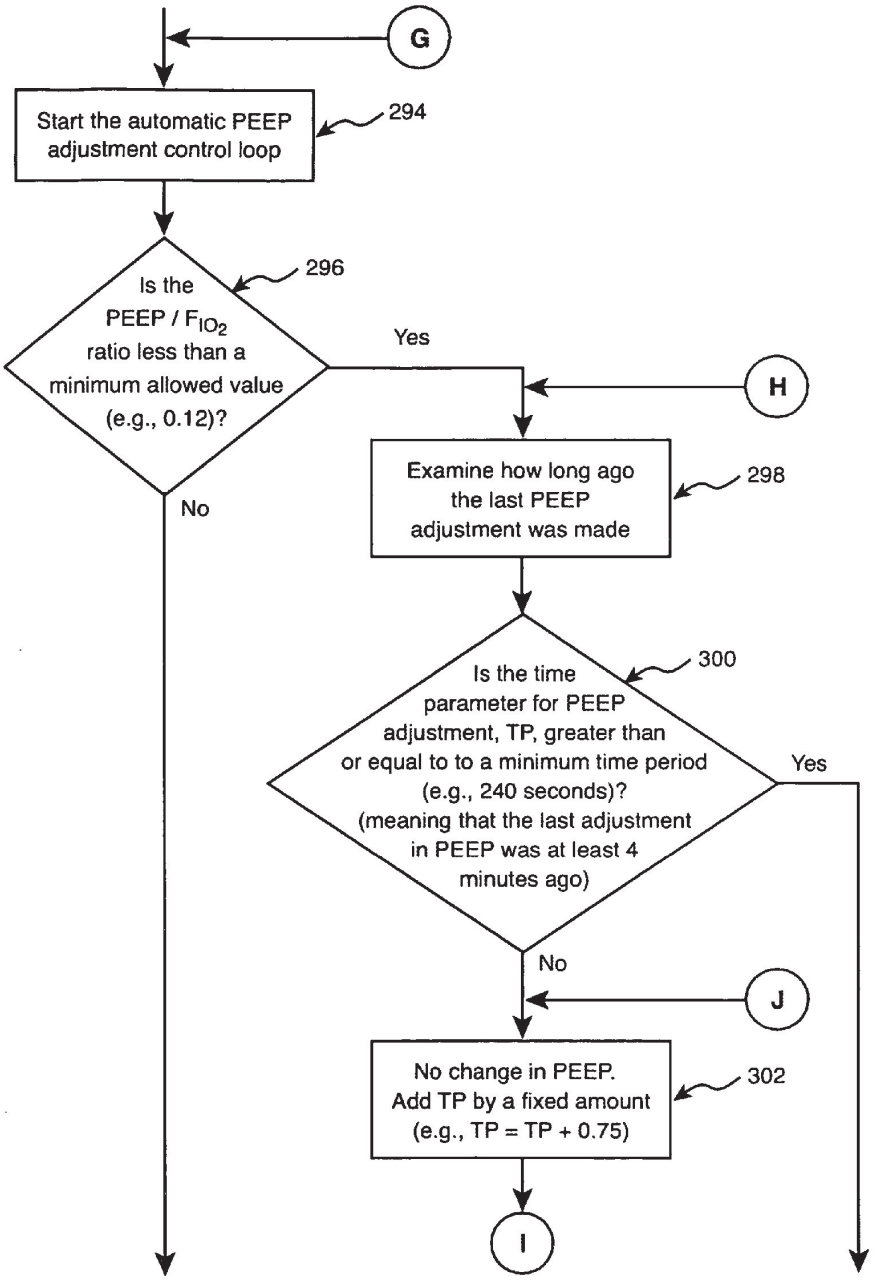

G
Start the automatic PEEP adjustment control loop
294
Is the PEEP / F_{IO_2} ratio less than a minimum allowed value (e.g., 0.12)?
296
Yes
No
H
Examine how long ago the last PEEP adjustment was made
298
Is the time parameter for PEEP adjustment, TP, greater than or equal to to a minimum time period (e.g., 240 seconds)? (meaning that the last adjustment in PEEP was at least 4 minutes ago)
300
Yes
No
J
No change in PEEP. Add TP by a fixed amount (e.g., TP = TP + 0.75)
302
I

Figure 3h

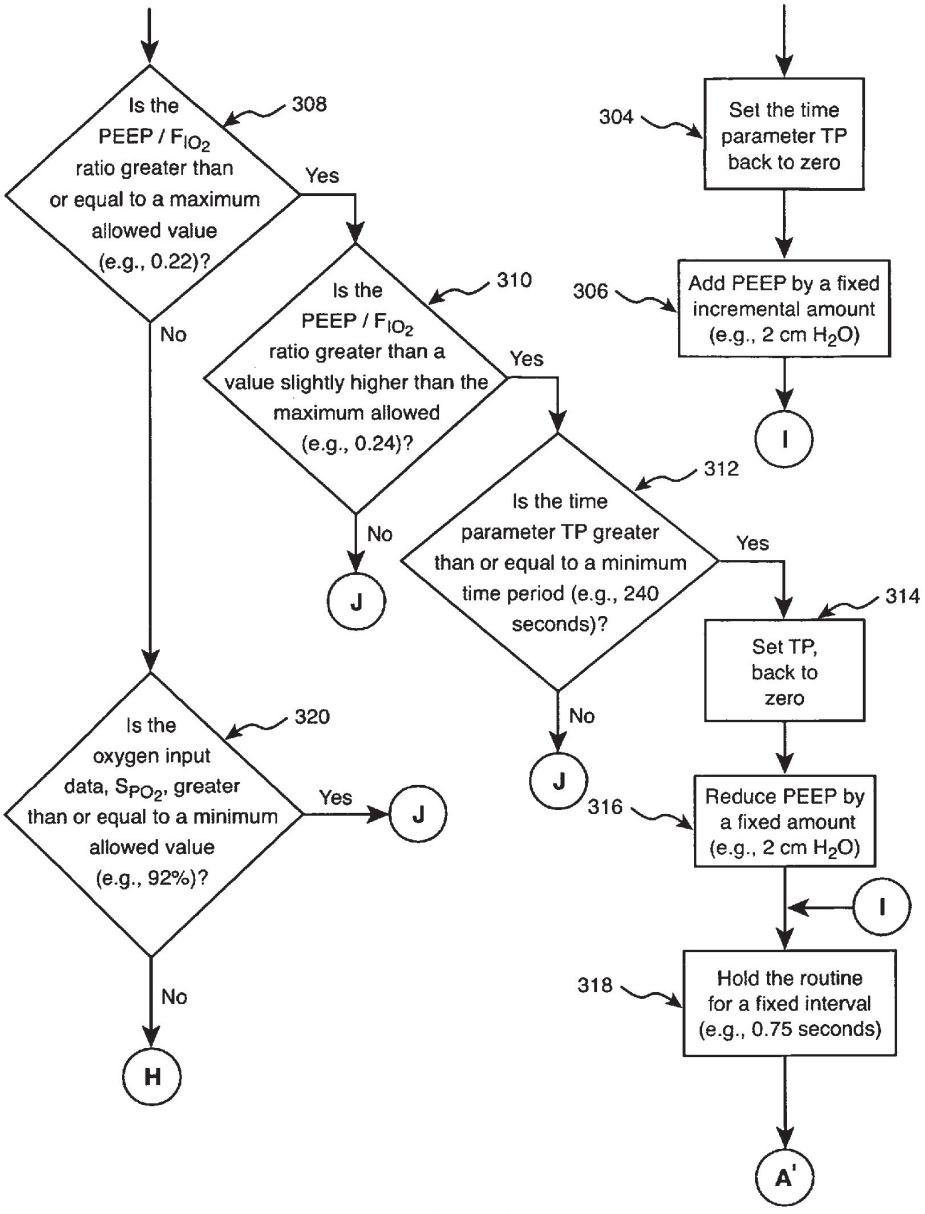

Is the PEEP / F_{IO_2} ratio greater than or equal to a maximum allowed value (e.g., 0.22)?
308
Yes
No
Is the PEEP / F_{IO_2} ratio greater than a value slightly higher than the maximum allowed (e.g., 0.24)?
310
Yes
No
J
Is the time parameter TP greater than or equal to a minimum time period (e.g., 240 seconds)?
312
Yes
No
J
Set the time parameter TP back to zero
304
Add PEEP by a fixed incremental amount (e.g., 2 cm H_2O)
306
I
Set TP, back to zero
314
Reduce PEEP by a fixed amount (e.g., 2 cm H_2O)
316
I
Hold the routine for a fixed interval (e.g., 0.75 seconds)
318
A'
Is the oxygen input data, S_{PO_2}, greater than or equal to a minimum allowed value (e.g., 92%)?
320
Yes
J
No
H

Figure 3i

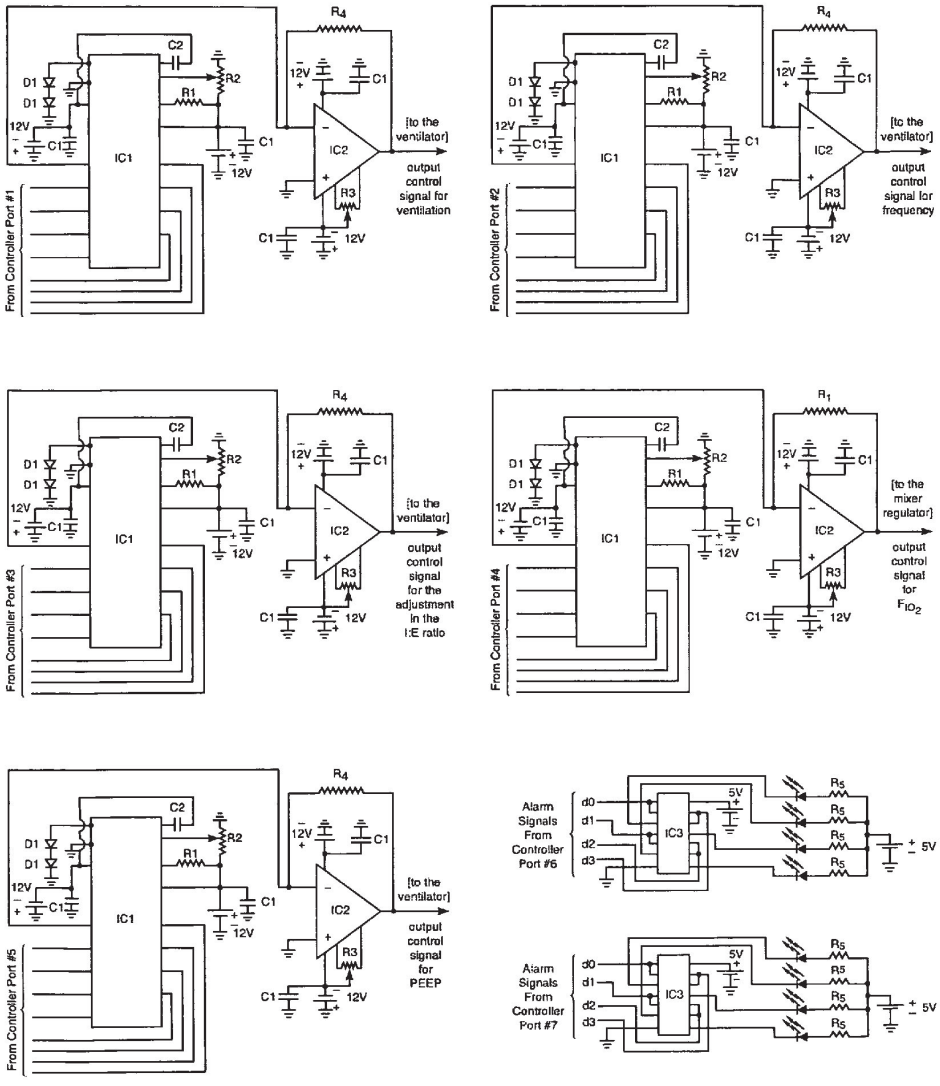

From Controller Port #1
From Controller Port #2
From Controller Port #3
From Controller Port #4
From Controller Port #5
Alarm Signals From Controller Port #6
Alarm Signals From Controller Port #7
IC1
IC2
IC3
R1
R2
R3
R4
R5
C1
C2
D1
12V
5V
[to the ventilator]
output control signal for ventilation
output control signal for frequency
output control signal for the adjustment in the I:E ratio
[to the mixer regulator]
output control signal for F_{IO_2}
output control signal for PEEP
d0
d1
d2
d3

Figure 4

METHOD AND APPARATUS FOR CONTROLLING A VENTILATOR

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. provisional patent application No. 60/481,693, filed Nov. 21, 2003, the entire contents of which are incorporated herein by reference. This application is related to U.S. Pat. No. 4,986,268 entitled "Method and Apparatus for Controlling an Artificial Respirator," the disclosure of which is incorporated by reference.

BACKGROUND OF INVENTION

1. Field of the Invention

The present invention relates to a method and apparatus for controlling a ventilator such as a mechanical ventilator (i.e. an artificial respirator) or a respiratory assist device. In particular, the present invention relates to a method and apparatus for controlling a ventilator based on the measured levels of oxygen of the patient on the ventilator, as well as other physical conditions of the patient.

2. Background of the Invention

Mechanical ventilators and other respiratory assist devices are extensively used to treat and manage all patient populations. In the past few decades, there have been significant changes in the features offered by the ventilators and they have become increasingly responsive to individual patient needs. However, despite much advancement in these devices, most ventilators used today are still mainly open-loop controlled devices and their added features have to some extent contributed to their complexity. The clinicians are required to make many important selections among the wide range of options available in advanced mechanical ventilators. Optimal adjustment of these machines oftentimes requires in depth knowledge about the ventilator along-with thorough review of the patient's status and his/her underlying illness. These adjustments are particularly cumbersome and frequent in more fragile and less medically stable patients.

There have been many attempts in the past to automatically control some of the main outputs of mechanical ventilators. See Y. Mitamura et al., "A dual control system for assisting respiration," Medical and Biological Engineering, vol. 13, no. 6, pages 846-854, 1975, Yu et al., "Improvement in arterial oxygen control using multiple model adaptive control procedures," IEEE Transactions on Biomedical Engineering, BME-34(8), pages 567-574, 1987, and U.S. Pat. No. 4,986,268 to F. T. Tehrani, issued Jan. 22, 1991, entitled "Method and apparatus for controlling an artificial respirator."

Also, see U.S. Pat. No. 5,103,814 to T. Maher, issued Apr. 14, 1992, entitled "Self-compensating patient respirator," Morozoff P. E., and Evans R. W., "Closed-loop control of S_{aO2} in the neonate," Biomedical Instrumentation and Technology, vol. 26, pages 117-123, 1992, U.S. Pat. No. 5,365,922 to D. B. Raemer issued Nov. 22, 1994 entitled "Closed-loop non-invasive oxygen saturation control system," Tehrani et al. "Closed-loop control of the inspired fraction of oxygen in mechanical ventilation," Journal of Clinical Monitoring and Computing, vol. 17, No. 6, pages 367-376, 2002, and U.S. Pat. No. 6,671,529 to N. R. Claure et al., issued Dec. 30, 2003, entitled "System and method for closed-loop controlled inspired oxygen concentration."

Some of the prior art on this subject is focused on controlling the patient's oxygenation, and some is intended to automatically control the breathing frequency and tidal volume. The systems intended for controlling only the oxygen level of the patient on the ventilator, either do not provide the automation of all factors that affect oxygenation and/or they do not provide a reliable and sufficiently robust response against oxygen disturbances.

In addition to advancement in mechanical ventilators, there have been many attempts in recent years to prevent the collapse of the airways and apnea in spontaneously breathing patients specially during sleep, by using less elaborate machines than mechanical ventilators, generally known as CPAP machines (CPAP stands for Continuous Positive Airway Pressure). In these machines, either a constant pressure is applied to the patient's airways throughout respiration (i.e. CPAP), or a combination of CPAP and pressure support in inspiration is used to ventilate the patient (e.g. bilevel CPAP machines). See U.S. Pat. No. 4,773,411 to J. B. Downs issued Sep. 27, 1988, entitled "Method and apparatus for ventilatory therapy," International Patent Publication No. WO 99/61088 to Resmed Limited, issued Dec. 2, 1999, entitled "Ventilatory assistance for treatment of cardiac failure and Cheyne-Stokes breathing," U.S. Pat. No. 6,539,940 to R. J. Zdrojkowski et al., issued Apr. 1, 2003, entitled "Breathing gas delivery method and apparatus," and U.S. Pat. No. 6,752,151 to P. D. Hill, issued Jun. 22, 2004, entitled "Method and apparatus for providing variable positive airway pressure."

In one embodiment, the present invention describes a method and apparatus that can reliably and robustly control PEEP (or CPAP), and F_{IO2}. These are novel features which significantly improve the oxygenation of patients during ventilatory therapy provided by mechanical ventilators as well as respiratory devices such as CPAP machines.

Furthermore, in a more elaborate embodiment of the invention, in addition to PEEP (or CPAP) and F_{IO2}, the I:E ratio of the patient can be automatically adjusted and by further inclusion of the features of U.S. Pat. No. 4,986,268, the breathing frequency, and tidal volume can be automatically controlled in mechanical ventilation. Application of these features results in a significantly more effective and optimal treatment to the patient based on his/her conditions and requirements, in total or assist ventilatory therapy.

SUMMARY OF INVENTION

A method and apparatus for controlling a ventilator includes first means receiving at least input data indicative of the patient's measured oxygen levels, and in a more elaborate embodiment of the invention, the first means also receives respiratory mechanics and/or pressure-volume data, as well as data indicative of measured carbon dioxide levels of the patient. The first means which preferably comprises a programmable microprocessor, is controlled by a software algorithm to operate on the input data, and to provide digital output data to control the ventilator and the gas mixer of the ventilator. The software algorithm is divided into two control programs. One control program which can either be used by itself or along with the other program, is designed to automatically adjust F_{IO2} and PEEP (or CPAP), based on at least the measured oxygen levels of the patient. The control program also operates on data from a pressure volume (PV) monitor/analyzer to set the initial PEEP value in certain groups of respiratory patients. The processing means detects hazardous conditions based on the input data and/or artifacts, replaces and/or corrects the measurement artifacts, and instructs generation of appropriate warning signals. The other control program, most of which is described in U.S. Pat. No. 4,986,268, is designed to control the frequency and ventilation for a next breath of the patient on the ventilator based on at least data indicative of measured CO_2 and O_2 levels of the

patient, barometric pressure (as a reference pressure), and respiratory elastance and airway resistance (respiratory mechanics) data; and to make necessary adjustments in the I:E ratio based on the patient's respiratory mechanics data. The output data from the 1st means indicative of PEEP (or CPAP), F_{IO2}, the adjustment in the I:E ratio, breathing frequency, and ventilation, and status of alarms are transmitted to a Signal Generator which is equipped with converters and/or other electronic components to generate the control and appropriate warning signals. The control signals for the breathing frequency, ventilation, PEEP (or CPAP), and the adjustment in the I:E ratio are supplied to the ventilator. The control signal for F_{IO2} is supplied to a mixer regulator unit which adjusts the concentration of oxygen added to the inhalation gas in the gas mixer of the ventilator. Based on the instructions from the 1st means, the alarm circuit generates appropriate warning signals when needed.

BRIEF DESCRIPTION OF DRAWINGS

FIGS. **1-4** illustrate a preferred embodiment of the present invention. However, it is understood that this invention is not limited to the precise arrangements shown in the figures and can be embodied in other arrangements without deviating from the scope of the invention.

FIG. **1** is a block diagram of a mechanical ventilator and the control apparatus according to an alternative embodiment of the invention.

FIGS. **2***a*-**2***c* show the flow chart of a software algorithm that also incorporates the control technique described in U.S. Pat. No. 4,986,268, to automatically control breathing frequency, tidal volume, and the adjustment in the I:E ratio of the patient on the ventilator, according to a preferred method of the present invention.

FIGS. **3***a*-**3***i* show the flow chart of a software algorithm to automatically control PEEP (or CPAP) and F_{IO2} according to a preferred method of the present invention.

FIG. **4** shows a preferred detailed schematic diagram of a Signal Generator and an Alarm Circuit, for use in a preferred practice of the present invention.

DETAILED DESCRIPTION

Definitions

In the specification and claims:

1—The term "ventilator" refers to a device which is used to provide total or assist ventilatory treatment to patients, and includes mechanical ventilators (i.e. artificial respirators) or CPAP (Continuous Positive Airway Pressure) machines.

2—The term "PEEP" represents "Positive End-Expiratory Pressure" and is interchangeable with the term "CPAP," which represents "Continuous Positive Airway Pressure," for example, when assist ventilation is provided to spontaneously breathing subjects.

3—The term "F_{IO2}" represents "concentration of oxygen in a patient's inspiratory gas" which is the same as "fraction of inspired oxygen."

4—The term I:E represents the "ratio of inspiration time to expiration time."

DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. **1** shows a block diagram according to an alternative practice of the present invention. The digital processor **10** includes a programmable controller coupled to receive the outputs of 8 bit A/D converters **12**, **14** and **16** as shown. The A/D converters **18** and **20** are each a single 8 bit A/D converter. The A/D converter unit **22** is an A/D board containing three 8 bit A/D converters. The inputs **24**, **26**, and **28** of the A/Ds are from an oxygen sensor, preferably a pulse oximeter, **30**, a CO_2 sensor, such as a transcutaneous monitor or preferably a capnograph, **32**, and a lung mechanics calculator and PV monitor, **34**. The outputs **24**, and **26** are each a single analog signal while the output **28** represents 3 analog signals; 1—representing respiratory elastance, 2—representing respiratory airway resistance (air viscosity factor in the lungs), and 3—representing the lower inflection point on the inspiratory or expiratory PV curve of the patient, or alternatively, the measured intrinsic PEEP (PEEPi) of the patient on the ventilator. The inputs to the oxygen sensor and the carbon dioxide sensor are respectively shown at **40** and **42** coming from the patient. The input **40** is preferably the arterial hemoglobin oxygen saturation data and the input to the CO_2 sensor shown at **42** is preferably the exhaled gas from the patient from which the end-tidal CO_2 concentration or the end-tidal partial pressure of CO_2 is determined by the sensor. The lung mechanics calculator and PV monitor, **34**, receives data from the mechanical ventilator shown at **56**, or from the patient through the ventilator circuit, on the line illustrated at **36** and communicates back to the ventilator as shown at **38**. The digital processor's outputs shown at **44** are applied to a Signal Generator Circuit, illustrated at **46**. The Signal Generator Circuit sends alarm instruction signals **52** to the alarm circuit **54**.

The mechanical ventilator **56** receives the control signals **48** from the Signal Generator Circuit **46**. These consist of signals to control PEEP, breathing frequency, tidal volume, and the adjustment in the I:E ratio of the patient. A Mixer Regulator circuit **58**, receives control signals to adjust F_{IO2}, **50**, from the Signal Generator Circuit **46**. An oxygen air mixer **62** receives the adjusted output signal **60** from the Mixer Regulator **58**. The concentration of oxygen in the mixer is thereby adjusted by mixing the determined concentration of oxygen **66** coming from the oxygen supply **70** and that of air **64** coming from the air compressor **68**. The enriched oxygenated air **72** from the mixer is provided to the ventilator **56** which delivers it to the patient at **74**.

Referring to FIG. **2***a*-**2***c*, there is illustrated a flow chart of the algorithm to control the breathing frequency, ventilation, and the adjustment in the I:E ratio in an alternative embodiment of the invention. As seen at the start of the flow chart, the initial values of breathing frequency and tidal volume are transmitted to the output ports in step **100**. Then the main loop at A is started and in the next step at **102**, based on data indicative of CO_2 and O_2 levels of the patient which are preferably provided by a capnograph and a pulse oximeter respectively, the arterial partial pressures of CO_2 and O_2 are calculated by using the following equations:

$$P_{aCO2}=P_{etCO2}+K_1$$

$$P_{aO_2}=\frac{-\ln\left[1-(S_{pO_2})^{0.5}\right]}{0.046}+CP$$

Where P_{aCO2} and P_{aO2} are arterial partial pressures of CO_2 and O_2 respectively, P_{etCO_2} is the end-tidal partial pressure of CO_2 measured by the CO_2 sensor, and K_1 is the difference between the arterial partial pressure of CO_2 and the end-tidal partial pressure of CO_2. K_1 can be measured in advance and

depending on the patient's conditions, it can be adjusted to set the desired P_{aCO2} of the patient. S_{pO2} is the arterial hemoglobin oxygen saturation of the patient measured by a pulse oximeter and CP is an added correction factor which is used to correct and shift P_{aO2} based on the patient's measured blood pH level. If the patient's blood pH level is in the 7.45-7.55 range, CP is set to zero. Otherwise, CP needs to be adjusted by +3.5 mm Hg per every −0.1 deviation in pH from the above range. After the calculation of P_{aCO2} and P_{aO2}, their values are compared to defined minimum acceptable levels to determine whether there has been any measurement artifact in step **104**. If any artifact is detected, the calculated value is discarded and the previous calculated value is resumed. In the next step at **106**, if P_{aCO2} and/or P_{aO2} are not within certain defined ranges, alarms are transmitted to the output ports. In the step that follows at **108**, if the calculated P_{aCO2} and P_{aO2} values are both lower than their minimum threshold limits (which are different from the minimum acceptable values used in step **104**), the possibility of pulmonary embolism is assumed, predefined levels of ventilation and breathing frequency are provided, and an alarm is generated in steps **110** and **112**, and the program returns to A. However, if the calculated P_{aCO2} and P_{aO2} values are not found to be simultaneously lower than their minimum threshold levels in **108**, then the effect of CO_2 on the required ventilation is calculated in step **114**:

$$V_C = C_1 \cdot P_{aCO2} - C_2$$

Where V_C is the ratio of alveolar ventilation as the net effect of CO_2 to the resting value of ventilation, C_1 is the sensitivity factor of the controller to CO_2 (e.g., C_1=0.405) and C_2 is a constant (e.g., C_2=14.88).

Next, in step **116**, the P_{aO2} value is compared to a high threshold limit of 104 mm Hg. If P_{aO2} is greater than or equal to this threshold value, the effect of oxygen on ventilation is set to zero in **118**, and the next step at **122** is followed. Otherwise, if P_{aO2} is found to be less than the threshold value in step **116**, then control is passed to step **120** in which the effect of oxygen on the required ventilation is calculated by using the following equation:

$$V_O = (4.72 \times 10^{-9})(104 - P_{aO2})^{4.9}$$

Where V_O is the ratio of alveolar ventilation as the net effect of oxygen to the resting value of ventilation. It is recognized that the above equations are based on the use of a capnograph and a pulse oximeter to measure the carbon dioxide and oxygen levels of the patient respectively. If other measurement techniques are utilized to provide data indicative of said levels, then other alternative equations may be used to determine the required ventilation for the patient, without deviating from the scope and the essential attributes of the invention.

In the next step at **122**, the effect of increase in the metabolic rate ratio, MRR, (i.e. rate of metabolism/basal rate of metabolism), on ventilation is calculated by using the following equation:

$$V_M = 0.988(MRR - 1)$$

Where V_M is the ratio of alveolar ventilation as the net effect of increase in the metabolic rate ratio, MRR, to the resting value of ventilation, and MRR is an input to the algorithm. In the next step at **124**, total alveolar ventilation for the next breath is calculated:

$$V_A = (V_A \text{ at rest})(V_C + V_O + V_M)$$

Where V_A is alveolar ventilation in liters/minute and V_A at rest is the alveolar ventilation at rest which is input and stored in the software. In the next step at **126**, the physiological dead space of the patient, and the total dead space including that of the equipment are calculated, if not provided in advance, as follows:

$$V_D = (0.1698 V_A/60) + 0.1587$$

$$V_{Dt} = V_D + V_{ED}$$

In these equations, V_D is the patient's dead space in liters, V_{ED} is the equipment dead space due to the tubes and connections, and V_{Dt} is the total dead space. It should be noted that the constant factors in these equations are based on measured experimental values for adults and can therefore be different for individual patients. Also, for other patient populations, they need to be adjusted. For example the constant factor of 0.1587 should change to a much smaller value for infants (e.g., 2.28×10^{-3}). In the next step at **128**, data indicative of barometric pressure and the patient's airway resistance (or the air viscosity factor in the lungs) and respiratory elastance are read from the input ports. The barometric pressure data which is affected mostly by the altitude, is used as a reference pressure (for the purpose of calibration) in the invention.

In the next step at **130**, the optimal frequency for the next breath is computed. This calculation is based on minimization of the respiratory work rate and is done in order to stimulate natural breathing, provide a more comfortable breathing pattern to the patient, and thereby, expedite the weaning process in assisted ventilation. The following equation, which is a modified version of an equation derived in 1950 by Otis et al. to describe the control of breathing frequency in mammals, is used to calculate the optimal breathing frequency in the invention:

$$f = \frac{-K' V_D + \sqrt{(K' V_D)^2 + 4K' K'' \Pi^2 V_{AR} V_D}}{2K'' \Pi^2 V_D}$$

where f is the optimum breathing frequency in breaths/second, V_{AR} is the alveolar ventilation in liters/second and is equal to V_A/60, K' is the respiratory elastance (reciprocal of respiratory compliance) in cm H_2O/liter and K" is the airway resistance in cm H_2O/liter/second. Next in step **132**, the required minute ventilation and tidal volume are calculated:

$$V_E = V_A + 60 f V_{Dt}$$

$$V_T = V_A/60f + V_{Dt}$$

Where V_E represents total minute ventilation in liters/minute and V_T is tidal volume in liters. In the next step at **134**, additional safety rules are applied. If breathing frequency, f, tidal volume, V_T, or minute ventilation are not within prescribed safe ranges, their values are limited and adjusted.

In the next step **136** which follows, the breathing frequency is compared with an upper limit value F_{max}. This upper limit frequency is defined as:

$$F_{max} = 1/5\tau$$

Where τ is the respiratory time constant and is equal to K"/K'. If in step **136**, the breathing frequency is found to be higher than F_{max}, then in the next step at **138**, its value is reduced to F_{max} (in which case V_T is also adjusted according to procedures in steps **132** and **134**), and step **140** is followed. Otherwise, if the computed breathing frequency is less than or equal to F_{max}, it does not need further adjustment and the program is transferred to step **140**. In step **140**, the expiration time, T_E, is compared to 2.5 times τ. If it is found to be less

than 2.5 τ, then step **142** is followed and the I:E ratio (the ratio of the inspiratory time to the expiratory time) is adjusted, so that T_E becomes at least equal to 2.5 τ. Otherwise, if T_E is found to be greater than or equal to 2.5 τ in step **140**, it does not need to be adjusted (i.e. the adjustment value is zero) and the program is transferred to step **144**. The reason for the adjustments in the breathing frequency and T_E in steps **138** and **142** mentioned above, is to provide sufficient time for exhalation based on the patient's respiratory time constant and to avoid build up of intrinsic positive end-expiratory pressure (PEEPi).

In step **144** that follows, the calculated values for ventilation, breathing frequency, and the adjustment in the I:E ratio for the next breath are provided to the output ports. At this point, if the ventilator is in the pressure control/assist mode, the inspiratory pressure is calculated by using the following equation:

$$P_m = K'V_T + PEEP$$

where P_m is the inspiratory pressure in cm H_2O. Thereafter, the control data indicative of P_m is also provided to an output port and the routine is held for the duration of the next breathing cycle. After the delay is passed, the program returns to the beginning of the loop at A.

It should be noted that the major portion of the procedure depicted in FIG. **2** to calculate the optimal breathing frequency and tidal volume of the breaths of a patient and controlling them automatically, has been described in U.S. Pat. No. 4,986,268. In the present invention, the necessary adjustments in the I:E ratio are controlled automatically as described above, and the levels of F_{IO2} and PEEP are automatically controlled by another algorithm which is described next.

Referring to FIGS. **3***a*-**3***i*, there is illustrated a flow chart of a control algorithm which is operated upon by the digital processor. This algorithm is either run by itself, or in an alternative embodiment of the invention, it is run in parallel to the algorithm of FIGS. **2***a*-**2***c* described above. The purpose of this algorithm is to automatically control the levels of F_{IO2} and PEEP provided to the patient on the ventilator and thereby improve the patient's oxygenation. The method depicted in FIGS. **3***a*-**3***i* can be used for patients on mechanical ventilation or those on respiratory assist devices receiving CPAP treatment. Depending on the type of the ventilatory treatment, the term PEEP in the flow chart is meant to be interchangeable with CPAP.

As is seen, at the start of the flow chart, the desired set point for arterial partial pressure of oxygen of the patient is defined in step **200**. This is done on the basis of the patient's conditions and his/her underlying illness. Then in the next step at **202**, the initial value of F_{IO2} is set and transmitted to the output port.

In step **204** that follows next, the initial value of PEEP is set and transmitted to an output port. The initial value of PEEP can be set by using different options. For certain patient groups such as COPD patients, the initial PEEP can be chosen to be 80% to 85% of the intrinsic PEEP (PEEPi) which needs to be measured in advance. For some other patient groups such as ARDS patients, the initial PEEP setting can be chosen to be 3-4 cm H_2O above the lower inflection pressure point of the inspiratory (or the expiratory) pressure volume curve of the patient. This value can either be calculated by the lung mechanics calculator and PV monitor unit and provided automatically to the digital processor via an input port, or the calculated value of the pressure can be provided manually by the clinician either through one of the input ports or via software. The third option is that the clinician arbitrarily decides an initial setting for PEEP and provides it to the digital processor, preferably via software. After setting the initial PEEP value in **204**, the next step in **206** is followed. At this point, a time parameter (e.g., TP) for PEEP adjustment is defined and initially set to zero. The purpose of defining this parameter is to guarantee that PEEP adjustments are done only after a certain time has elapsed since the latest adjustment, thereby giving enough time to an adjustment in PEEP to make an impact on the patient's oxygenation.

In step **208** which follows next, another parameter, AP, for PEEP adjustment is defined. If this parameter is set to zero, then PEEP is controlled manually and only F_{IO2} is automatically adjusted. If AP is set to one, then both F_{IO2} and PEEP are automatically controlled.

In the next step **210**, the threshold values for arterial hemoglobin oxygen saturation, S_{pO2}, (or alternatively for arterial partial pressure of oxygen) are defined. In a preferred practice of the invention, four threshold values are defined for S_{pO2} and they are set at 90%, 93%, 95%, and 97% respectively. However, the threshold values may differ for different patients. They should be defined based on the patient's conditions and the desired levels of oxygenation.

Next, program control passes to step **212** in which a loop indicator (e.g., LI) is defined and is set to 1.5, and the main loop starts at A'.

In the next step in **214**, the patient's S_{pO2} data is read from one of the input ports, and in step **216**, the arterial partial pressure of oxygen is calculated from the S_{pO2} data as:

$$P_{aO_2} = \frac{-\ln\left[1 - (S_{pO_2})^{0.5}\right]}{0.046} + CP$$

Where P_{aO2} is the arterial partial pressure of oxygen, and CP is an added correction factor which is used to shift P_{aO2} based on the patient's measured blood pH level. If the patient's blood pH is within 7.45-7.55, then CP is set to zero. Otherwise, for every +0.1 deviation in pH from this range, CP is adjusted by −3.5 mm Hg as was also mentioned in the description of FIG. **2** earlier.

In step **218** that follows next, the calculated partial pressure of oxygen, P_{aO2}, is compared with a minimum acceptable value. This is done to detect artifacts in the measurement of S_{pO2}. If the calculated P_{aO2} is found to be less than the minimum acceptable value, then control passes to step **220** in which an artifact is assumed and an alarm is generated. Then step **222** is performed in which the S_{pO2} data is discarded and the previous value Of P_{aO2} in the memory is resumed and step **224** is followed. However, if in **218**, the calculated P_{aO2} is found to be greater than or equal to the minimum acceptable value, its value is accepted and control passes to step **224**.

In step **224**, S_{pO2} is compared to a minimum safe value, which is the first threshold value defined previously in step **210** (e.g., 90%). If S_{pO2} is less than or equal to the minimum safe value, loop B is started in **226** and the loop indicator, LI, is set to 2.5. Then in step **228**, F_{IO2} is increased stepwise (i.e. in a step-like arrangement) to a high value, F1, (e.g., 60%), and an alarm is generated in **230**. Control then passes to loop F at which the procedure of PEEP adjustment begins as will be described later. However, if S_{pO2} is found to be higher than the minimum safe value in step **224**, control passes to **232** where S_{pO2} is compared to a second threshold value (e.g., 93%). If S_{pO2} is less than the second threshold value, then steps **234** and **236** are followed in which the loop indicator, LI, is examined and compared to 2. If LI is less than 2, control passes to another loop E which will be described later. If LI is

greater than or equal to 2, the next step in **238** is performed in which LI is compared to 3. If LI is less than 3, control passes to loop B (where F_{IO2} was set high at F1, e.g., 60%), otherwise, the program transfers to step **240**. In this step, LI is compared to 4. If it is less than 4, control passes to loop C; otherwise, the program transfers to loop D (loops C and D will be described later).

Back to step **232**, if S_{pO2} is found to be higher than or equal to the 2^{nd} threshold value (e.g., 93%), then steps **242** and **244** are followed in which LI is compared to 2. If it is less than 2, control passes to loop E. Otherwise, in the next step at **246**, LI is compared to 3. If less than 3, loop C is defined and started at **248**, and LI is set to 3.5. Then in step **250**, F_{IO2} is set stepwise at a moderately high value, F2 (e.g., 45%), and control transfers to loop F in which the procedure of PEEP adjustment is followed. However, if in step **246**, LI is found to be greater than or equal to 3, control passes to step **252** in which LI is compared to 4. If LI is less than 4, then S_{pO2} is compared to a third threshold value (e.g., 95%) in step **254**. If S_{pO2} is less than the third threshold value, control passes to loop C in which F_{IO2} was set at a moderately high level, F2 (e.g., 45%). Otherwise, if S_{pO2} is found to be higher than or equal to the third threshold value in **254**, then the next step in **256** is followed in which loop D is defined and started and LI is set to 4.5. Next in step **258**, F_{IO2} is set stepwise at a slightly high level, F3 (e.g., 30%), and control passes to loop F.

Back to step **252**, if LI is found to be greater than or equal to 4, then S_{pO2} is compared to a 4^{th} threshold value (e.g., 97%) in step **260**. If S_{pO2} is less than the 4^{th} threshold value, control passes to loop D in which F_{IO2} was set at a slightly high value, F3 (e.g., 30%). Otherwise, if S_{pO2} is higher than or equal to the 4^{th} threshold value in **260**, then loop E is started in **262** and LI is set to 1.5. In loop E, a proportional, integral, derivative (PID) control procedure is performed to adjust F_{IO2} (PID control is a control technique comprising proportional, integral, and derivative terms). In the next step at **264**, using the P_{aO2} set point defined in step **200**, the proportional, differential, and integral components of error are calculated as follows:

$$Y_1(k)=P_{aO2}(\text{set-point})-P_{aO2}$$

$$Y_2(k)=[Y_1(k)-Y_1(k-1)]/T$$

$$Y_3(k)=Y_3(k-1)+TY_1(k)$$

In the above equations, $Y_1(k)$, $Y_2(k)$, and $Y_3(k)$ represent the proportional, differential, and integral components of error in P_{aO2} respectively, and T is a sampling interval.

In step **266** that follows, the required F_{IO2} is calculated by using the following equations:

$$E(k)=\alpha Y_1(k)+\beta Y_3(k)+\gamma Y_2(k)$$

$$G(k)=E(k)+0.21$$

Where E(k) is an error function, α, β, and γ are the PID coefficients, and G(k) is the required F_{IO2}. In a preferred practice of the invention, T is set to 0.75 seconds, and α, β, and γ are set to 6.45×10^{-5}, 3.22×10^{-5}, and 7.29×10^{-6} respectively. These parameters were tuned to minimize steady-state oscillations and to keep the overshoot/undershoot in the F_{IO2} response of the PID controller below 25% of the total change. It is also recognized that other error correction schemes can be used to determine F_{IO2}. As long as those schemes reduce the error in the oxygen level of the patient in a similar way as described above, they will be within the scope of the present invention.

In the next step in **268**, the calculated value of F_{IO2} is compared with a minimum of 0.21 (i.e. 21%). If the F_{IO2} value is less than 21%, in step **270** which follows, it is set to a minimum of 21% and control passes to loop F. However, if in **268**, F_{IO2} is found to be greater than or equal to 21%, control passes to step **272** in which F_{IO2} is compared to a maximum allowed value (e.g., 80%). If F_{IO2} is less than or equal to the maximum allowed value, the next step in **274** is followed where the calculated value of F_{IO2} is sent to the output port and control passes to step **276**. In this step F_{IO2} is compared to 60%. If it is less than 60%, control passes to loop F. Otherwise, an alarm is generated in **278** and then control transfers to loop F.

Back to step **272**, if the calculated value of F_{IO2} is found to be higher than the maximum allowed value, it is reduced to the maximum value in step **280**, an alarm is generated, and then control transfers to loop F.

Up to the beginning of loop F at step **282**, the focus of control is on automatic control of F_{IO2}. As shown, two different mechanisms are incorporated in the control process of F_{IO2} in a preferred practice of the invention. One, a rapid stepwise control scheme which responds instantly to fast declines in S_{pO2}, and the other, a more finely controlled PID algorithm that provides fine control of F_{IO2} in the absence of sharp and hazardous declines in S_{pO2}. The stepwise controller in a preferred practice of the invention has three loops, each with its defined minimum and maximum S_{pO2} threshold levels. These three loops were shown respectively at B, C, and D, and the PID control loop was shown at E in the flow chart of FIG. **3**. The controller switches from the PID control to the rapid stepwise algorithm only if rapid declines in S_{pO2} are detected. Once in the stepwise mode, the controller continuously checks S_{pO2}, and if it rises, the controller reduces F_{IO2} to minimize the exposure of the patient to high and toxic levels of F_{IO2}. The controller is designed to correct hypoxemia within seconds and to avoid hyperoxemia. As shown, the controller detects artifacts in the measurement of S_{pO2}, discards the artifacts, and generates alarms when appropriate. The algorithm also enables clinicians to define the desired oxygenation levels for different patients. This is done by defining an appropriate P_{aO2} set point, by setting the threshold values for S_{pO2}, and by adjusting the correction parameter, CP, in accordance with the measured pH levels in the patient's blood as described above.

After the determination of the required F_{IO2}, the procedure of adjusting the PEEP value is started at F in step **282**. In this step, the ratio of PEEP/F_{IO2} is calculated. Then in **284**, the control parameter AP, which was defined in step **208**, is examined. If it is less than 1, it means that PEEP is not adjusted automatically and it is instead adjusted manually by the operator. In this case, the controller merely watches the PEEP/F_{IO2} ratio and generates warning signals, if the ratio is either too low or too high. In step **286**, the ratio is compared to a minimum allowed value (e.g., 0.12). If it is less than the minimum value, an alarm is generated in **288** and control passes to I (which will be described later). However, if the PEEP/F_{IO2} ratio is found to be equal to or greater than the minimum value in step **286**, then the next step in **290** is performed where the ratio is compared to a maximum allowed value (e.g., 0.22). If the ratio is less than or equal to the maximum value, control passes to I. Otherwise, an alarm is generated in step **292** and then control is transferred to I.

Back to step **284**, if AP is not less than 1, it means that PEEP should be calculated and automatically adjusted. Therefore, the automatic PEEP adjustment control loop is started next at G at step **294**. In the step **296** that follows, the PEEP/F_{IO2} ratio is compared to a minimum allowed value (e.g., 0.12). If it is less than the minimum, the procedure at H is started and it is examined how long ago the last adjustment in PEEP was

made. In step **300** that follows, the time parameter, TP, is compared to a defined fixed interval, T1, for example 240 seconds. If TP is less than 240 seconds, it means that the last PEEP adjustment was made less than 4 minutes ago. Then the procedure at J is started. Control passes to step **302** in which no change is made in PEEP and the time parameter, TP, is increased by a fixed amount (e.g., 0.75 seconds):

$$TP_{(new)}=TP_{(old)}+0.75$$

Thereafter, control passes to I. However, if in step **300**, it is found that TP is equal to or greater than 240 seconds, it means that the last adjustment in PEEP was made at least 4 minutes ago or longer. Therefore, control passes to step **304**. In this step, TP is set back to zero. Then in **306** that follows, PEEP is increased by a fixed amount (e.g., 2 cm H_2O):

$$PEEP_{(new)}=PEEP_{(old)}+2 \text{ cm } H_2O$$

Thereafter, control passes to I.

Back to step **296**, if the PEEP/F_{IO2} ratio is not found to be less than the minimum allowed value, control transfers to step **308**. In this step the PEEP/F_{IO2} ratio is compared to a maximum allowed value (e.g., 0.22). If the ratio is not less than the maximum value, step **310** is next performed. At this point, the PEEP/F_{IO2} ratio is compared to a slightly higher value than the maximum, RG, (e.g., 0.24). If it is not greater than this value, control passes to J. Otherwise; step **312** is performed in which the time parameter, TP, is compared to the fixed interval of 240 seconds. If TP is less than 240 seconds, control passes to J. Otherwise; TP is set back to zero in step **314**, and PEEP is reduced by a fixed amount (e.g., 2 cm H_2O) in step **316**:

$$PEEP_{(new)}=PEEP_{(old)}-2 \text{ cm } H_2O$$

Thereafter, control passes to I. In step **318** at I, the routine is held for a fixed interval (e.g., 0.75 seconds) and then control returns to the beginning of the main loop at A'.

Back to step **308**, if the PEEP/F_{IO2} ratio is found to be less than the maximum allowed limit (e.g., 0.22), the step **320** is next followed. In this step S_{pO2} is compared to a predefined minimum allowed value (e.g., 92%). If it is higher than or at least equal to the predefined minimum value, the PEEP level is not changed and control passes to J. However, if in **320**, S_{pO2} is found to be less than the predefined minimum value, then control passes to H, where it is determined whether at least 4 minutes have passed since the last PEEP adjustment, and if so, PEEP is increased by a fixed amount (e.g., 2 cm H_2—O) as was shown earlier.

In performing the automatic PEEP adjustments, the PEEP/F_{IO2} is kept within a clinically acceptable range. As shown above, if the PEEP/F_{IO2} is too low, PEEP is increased by a fixed increment (e.g., 2 cm H_2O). Also, if the PEEP/F_{IO2} ratio is within the acceptable range and S_{pO2} is low, then PEEP is increased by a fixed increment (e.g., 2 cm H_2O) to improve patient's oxygenation. On the other hand, if the PEEP/F_{IO2} ratio increases beyond a maximum defined value, the program reduces PEEP in fixed amounts (e.g., 2 cm H_2O). In any case, the interval between two successive PEEP adjustments is at least equal to a fixed period (e.g., 240 seconds), to allow for the changes in PEEP to have an observable and measurable impact on the patient's oxygenation.

It should be noted that the above examples for the incremental step size for PEEP adjustment (e.g. 2 cm H_2O) and the minimum and maximum values for the ratio of PEEP/F_{IO2}, are indicated for patients receiving ventilatory treatment in a more acute clinical setting such as the intensive care or a constant care unit of a hospital. Smaller incremental adjustments (e.g. 1 cm H_2O) and more conservative ranges for the ratio of PEEP (or CPAP)/F_{IO2} may be adopted if the invention is used to improve the breathing and oxygenation of more stable, spontaneously breathing patients.

FIG. **4** illustrates in detail, a preferred circuit diagram of the Signal Generator Circuit, **46**, and the alarm circuit **54**. The preferred component types and values are shown in the chart below:

Component	Type/Value
IC1	DAC0802LCN
IC2	LM741CN
IC3	SN7400N
C1	0.1 μF
C2	0.03 μF
D1	1N4148
R_1	5.1 kΩ
R_2	50 kΩ pot
R_3	10 kΩ pot
R_4	2.7 kΩ
R_5	330 Ω

There has been described a method and apparatus for controlling a ventilator. The invention utilizes data indicative of measured oxygen levels of the patient to automatically control F_{IO2}, and PEEP (or CPAP). In an alternative embodiment, the invention further uses the respiratory mechanics data (i.e. respiratory elastance and airway resistance) to automatically make the necessary adjustments in the I:E ratio of the patient on the ventilator. It further incorporates the features of U.S. Pat. No. 4,986,268 and uses data indicative of measured levels of oxygen and the respiratory mechanics data of the patient, along with data indicative of barometric pressure (as a reference calibrating pressure), and data indicative of measured carbon dioxide level of the patient to automatically control the breathing frequency and tidal volume of breaths of the patient on the ventilator. The invention also detects and corrects artifacts in the measured oxygen and carbon dioxide data and applies safety rules. In its different embodiments, the invention can improve total and/or assist ventilatory treatments provided to different patient groups.

The present invention may be embodied in other specific forms without departing from the scope and the essential attributes thereof. Therefore, reference should be made to the appended claims rather than to the foregoing specification, with regard to the scope of the invention.

What is claimed is:

1. An apparatus for automatically controlling a ventilator comprising:

first means for processing data indicative of at least a measured oxygen level of a patient, and for providing output data indicative of:

required concentration of oxygen in inspiratory gas of the patient (F_{IO2}) and positive end-expiratory pressure (PEEP) for a next breath of the patient;

wherein F_{IO2} is determined to reduce the difference between the measured oxygen level of the patient and a desired value;

wherein PEEP is determined to keep a ratio of PEEP/F_{IO2} within a prescribed range and, while keeping the ratio within the prescribed range, to keep the measured oxygen level of the patient above a predefined value; and

second means, operatively coupled to the first means, for providing control signals, based on the output data provided by the first means, to the ventilator;

wherein the control signals provided to the ventilator automatically control PEEP, and F_{IO2}, for a next breath of the patient.

2. The apparatus of claim **1**, wherein the first means comprises a programmable microcomputer.

3. The apparatus of claim **2**, further comprising

an alarm unit;

wherein the first means further determines whether there has been an artifact in the measured oxygen levels and replaces and/or corrects the data determined to be based on the artifact; and

wherein the second means further provides an alarm control signal to the alarm unit to warn of the artifact in the measured oxygen levels.

4. The apparatus of claim **2**, further comprising

an alarm unit;

wherein the first means further determines whether the measured oxygen levels are outside a prescribed range; and

wherein the second means further provides an alarm control signal to the alarm unit to warn of the measured oxygen level of the patient being outside a prescribed range.

5. The apparatus of claim **2**, further comprising an analog to digital (A/D) converter connected to an input of the first means for converting analog signals from an oxygen sensor, indicative of the oxygen level of the patient, to digital data.

6. The apparatus of claim **5**, wherein the oxygen sensor is a pulse oximeter measuring arterial hemoglobin oxygen saturation in the patient's blood.

7. The apparatus of claim **2**, wherein data indicative of the lower inflection pressure point on an inspiratory or expiratory pressure volume curve of the patient (LIP) is provided to the first means.

8. The apparatus of claim **7**, wherein the data indicative of LIP is supplied by a monitor operatively coupled to the first means.

9. The apparatus of claim **2**, wherein data indicative of the patient's measured intrinsic positive end-expiratory pressure (PEEPi) is provided to the first means.

10. The apparatus of claim **9**, wherein the data indicative of PEEPi is supplied by a monitor operatively coupled to the first means.

11. The apparatus of claim **2**, wherein the programmable microcomputer further comprises a program means for determining from the input data: the patient's arterial partial pressure of oxygen; the required F_{IO2}; the required PEEP; for a next breath of the patient.

12. The apparatus of claim **11**, wherein the program means further determines, from the input data: whether there has been an artifact in the data indicative of the measured oxygen level of the patient, and wherein the program means further replaces and/or corrects the data based on the artifact and generates a warning signal in the event the artifact is determined.

13. The apparatus of claim **2**, wherein data corresponding to a set point for arterial partial pressure of oxygen, threshold values for the oxygen level of the patient, and a correction factor for oxygen based on measured blood pH levels of the patient are entered manually and stored in a software program.

14. The apparatus of claim **2**, wherein the first means further processes input data indicative of respiratory elastance, respiratory airway resistance, barometric pressure, and measured carbon dioxide levels of the patient, and based upon the input data, provides digital output data indicative of required ventilation, optimum breathing frequency, and required adjustment in the ratio of inspiration time to expiration time (I:E) for a next breath of the patient, and; wherein the second means further generates additional control signals to the ventilator based on the output data of the first means; wherein the additional control signals to the ventilator control tidal volume and frequency of inhaled gas provided to the patient by the ventilator and effect necessary adjustments in the ratio of I:E for a next breath of the patient.

15. The apparatus of claim **14**, wherein the input data indicative of respiratory elastance and airway resistance of the patient are supplied to the first means by one or more monitors coupled to the first means.

16. The apparatus of claim **14**, wherein the input data indicative of respiratory elastance and airway resistance of the patient are entered manually and stored in a software program.

17. The apparatus of claim **14**, wherein the input data indicative of the measured oxygen level of the patient and the measured carbon dioxide level of the patient are provided to the first means by one or more monitors coupled to the first means.

18. The apparatus of claim **17**, wherein the input data indicative of the measured oxygen level of the patient is provided by a pulse oximeter measuring arterial hemoglobin oxygen saturation of the patient, and the input data indicative of the measured carbon dioxide level of the patient is provided by an exhaled gas analyzer detecting end-tidal partial pressure of carbon dioxide or end-tidal concentration of carbon dioxide in exhaled gas of the patient.

19. The apparatus of claim **17**, wherein, based on data indicative of measured oxygen and carbon dioxide levels of the patient, the first means detects an artifact in the data, discards the data having the artifact, resumes a previous value of the data in a memory, and provides a warning instruction signal; and wherein the second means generates a warning control signal that is supplied to an alarm unit that generates an alarm signal.

20. The apparatus of claim **17**, wherein, based on data indicative of measured carbon dioxide and oxygen levels of the patient, the first means detects a potential pulmonary embolism and produces digital output data indicative of predefined levels of ventilation and breathing frequency and a required adjustment in the I:E ratio, and provides a warning instruction signal; and wherein the second means generates a warning control signal.

21. The apparatus of claim **17**, further comprising program means for determining from the input data: (i) partial pressures of oxygen and carbon dioxide in arterial blood of the patient; (ii) presence of artifact(s) in the data indicative of the measured oxygen and carbon dioxide levels of the patient, and in case of artifact detection, replacing and/or correcting the data and corresponding partial pressure value(s); (iii) net effects of oxygen and carbon dioxide on alveolar ventilation; (iv) total required alveolar ventilation; (v) optimal frequency of breathing; (vi) required ventilation; (vii) required adjustment in the I:E ratio; (viii) required F_{IO2}; and (ix) required PEEP; for a next breath of the patient.

22. The apparatus of claim **21**, wherein data corresponding to a set point for arterial partial pressure of oxygen, an adjustment factor for carbon dioxide level of the patient, threshold levels for oxygen level of the patient, and a correction factor for oxygen based on measured blood pH levels of the patient, are entered manually and stored in a software program.

23. The apparatus of claim **14**, wherein the input data indicative of barometric pressure is supplied to the first means by one or more monitors coupled to the first means.

24. The apparatus of claim **14**, wherein the input data indicative of barometric pressure is entered manually and stored in hardware.

25. The apparatus of claim **14**, wherein the input data indicative of barometric pressure is entered manually and stored in a software program.

26. The apparatus of claim **14**, wherein the first means also receives and processes data indicative of the patient's metabolic rate ratio.

27. The apparatus of claim **26**, wherein the data indicative of the patient's metabolic rate ratio is supplied to the first means by a monitor coupled to the first means.

28. The apparatus of claim **26**, wherein the data indicative of the patient's metabolic rate ratio is entered manually and stored in a software program.

29. A method for automatically controlling a ventilator comprising the steps of:

(a) measuring an oxygen level of a patient and providing a data signal indicative of the measured oxygen level;

(b) determining: (i) required concentration of oxygen in an inspiratory gas of the patient, F_{IO2}, based on the data signal indicative of the measured oxygen level of the patient and to reduce the difference between the measured oxygen level of the patient and a desired value; (ii) required positive end-expiratory pressure, PEEP, wherein a ratio of PEEP/F_{IO2} is maintained within a prescribed range, and to keep the measured oxygen level of the patient above a predefined value; and

(c) providing data signals indicative of the required F_{IO2} and the required PEEP based upon the determining of step (b), for automatically controlling F_{IO2} and PEEP for a next breath of the patient.

30. The method of claim **29**, wherein step (b) further comprises determining, from the data indicative of the measured oxygen level in (a), whether there has been an artifact in the measured oxygen level, and replacing and/or correcting the data signal in (a) in the event the artifact is determined.

31. The method of claim **29**, wherein the data signal indicative of measured oxygen level of the patient is in analog form and is converted to digital form before the determining of step (b), and wherein the providing of step (c) further comprises converting the data signals from digital to analog form.

32. The method of claim **31**, wherein the measuring of the oxygen level of the patient comprises measuring an arterial hemoglobin oxygen saturation of the patient via pulse oximetry.

33. The method of claim **32**, wherein an arterial partial pressure of oxygen of the patient is derived from the arterial hemoglobin oxygen saturation of the patient measured by the pulse oximeter.

34. The method of claim **33**, wherein the following equation is used to calculate the arterial partial pressure of oxygen (P_{aO2}) of the patient from the arterial hemoglobin oxygen saturation data (S_{pO2}) measured by pulse oximetry:

$$P_{aO_2} = \frac{-\ln\left[1-(S_{pO_2})^{0.5}\right]}{0.046} + CP$$

where P_{aO2} is in mm Hg and CP is a correction parameter which is used to shift P_{aO2} and CP is based on the patient's measured blood pH level.

35. The method of claim **34**, further comprising:

comparing P_{aO2} to a minimum acceptable value, and,

if P_{aO2} is found to be less than the minimum acceptable value:

discarding P_{aO2} and a latest measured S_{pO2} data;

resuming previous values of P_{aO2} and S_{pO2}; and

generating a warning signal.

36. The method of claim **29**, wherein data corresponding to the lower inflection pressure point on an inspiratory or expiratory pressure volume curve of the patient (LIP) is also provided in step (a), and an initial value for PEEP is set equal to LIP plus 0 to 8 cm H_2O and the initial value for PEEP is provided in step (b).

37. The method of claim **36**, wherein the data corresponding to LIP is supplied by a monitor.

38. The method of claim **29**, wherein data corresponding to the measured intrinsic PEEP of the patient (PEEPi) is also provided in step (a), and an initial value for PEEP is set between 80% and 100% of PEEPi and the initial value for PEEP is provided in step (b).

39. The method of claim **38**, wherein the data corresponding to PEEPi is supplied by a monitor.

40. The method of claim **29**, wherein an initial value for PEEP is determined by the operator and is manually provided.

41. The method of claim **29**, wherein the required concentration of oxygen in the inspiratory gas of the patient (F_{IO2}) is calculated by using a stepwise control scheme and/or by using a proportional-integral-derivative (PID) technique.

42. The method of claim **41**, wherein using a PID technique comprises comparing S_{pO2} obtained by pulse oximetry to a defined minimum safe value, and wherein using the PID technique continues while S_{pO2} is greater than the defined minimum safe value.

43. The method of claim **41**, wherein using a PID technique comprises comparing S_{pO2} obtained by pulse oximetry to a defined minimum safe value, and wherein, if S_{pO2} is found to be less than or equal to the defined minimum safe value, a stepwise control scheme is followed that comprises the steps of:

raising F_{IO2} stepwise to avoid hypoxemia,

allowing F_{IO2} to remain high until S_{pO2} rises to a second threshold value,

lowering F_{IO2} stepwise,

comparing S_{pO2} to a third threshold value,

lowering F_{IO2} stepwise upon S_{pO2} rising to the third threshold value,

comparing S_{pO2} to a fourth threshold value,

returning control to the PID technique upon S_{pO2} rising to the fourth threshold value.

44. The method of claim **41**, wherein the difference between a P_{aO2} set point and the P_{aO2} of the patient is reduced by using a PID control procedure according to the following equations:

$$Y_1(k)=P_{aO2}(\text{set-point})-P_{aO2}$$

$$Y_2(k)=[Y_1(k)-Y_1(k-1)]/T$$

$$Y_3(k)=Y_3(k-1)+TY_1(k)$$

$$E(k)=\alpha Y_1(k)+\beta Y_3(k)+\gamma Y_2(k)$$

$$G(k)=E(k)+0.21$$

where $Y_1(k)$, $Y_2(k)$, and $Y_3(k)$ are the proportional, derivative, and integral components of error, respectively, E(k) is an error function, T is a sampling interval, G(k) is the required F_{IO2}, and parameters α, β, and γ are PID coefficients.

45. The method of claim **41**, wherein the determining of required PEEP of the patient comprises the following procedure:

comparing the PEEP/F_{IO2} ratio to a defined minimum allowed value,

increasing PEEP by a fixed incremental value if the PEEP/F_{IO2} ratio is lower than the defined minimum allowed

value and the time elapsed since the last adjustment in PEEP is longer than or equal to a fixed defined interval T1,

comparing the PEEP/F_{IO2} ratio with a defined maximum allowed value if the PEEP/F_{IO2} ratio is not less than the defined minimum allowed value,

comparing S_{pO2} with a defined value if the PEEP/F_{IO2} ratio is less than the defined maximum allowed value,

increasing PEEP by a fixed incremental value if S_{pO2} is less than the defined value and the time elapsed since the last adjustment in PEEP is longer than or equal to T1,

if the PEEP/F_{IO2} ratio is not less than the defined maximum allowed value, comparing the PEEP/F_{IO2} ratio to a value higher than the defined maximum allowed value, RG, whereby if the PEEP/F_{IO2} ratio is higher than RG, and the time elapsed since the last adjustment in PEEP is greater than or equal to T1, decreasing PEEP by a fixed incremental amount.

* * * * *

US005388575A

United States Patent [19]

Taube

[11] Patent Number: 5,388,575

[45] Date of Patent: Feb. 14, 1995

[54] **ADAPTIVE CONTROLLER FOR AUTOMATIC VENTILATORS**

[76] Inventor: **John C. Taube**, 1531 Hanover St., Raleigh, N.C. 27608

[21] Appl. No.: **950,897**

[22] Filed: **Sep. 25, 1992**

[51] **Int. Cl.**[6] **A61M 16/00**

[52] **U.S. Cl.** **128/204.23**; 128/203.14; 128/716

[58] **Field of Search** 128/204.23, 713–716, 128/204.21, 203.14

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,414,747	1/1947	Kirschbaum .	
3,734,091	5/1973	Taplin	128/204.23
4,326,513	4/1982	Schulz	128/203.14
4,584,996	4/1986	Blum	128/204.21
4,665,911	5/1987	Williams	128/204.21
4,889,116	12/1989	Taube	128/204.23
5,003,985	4/1991	White	128/716
5,103,814	4/1992	Maher	128/204.18
5,178,151	1/1993	Sackner	128/672

OTHER PUBLICATIONS

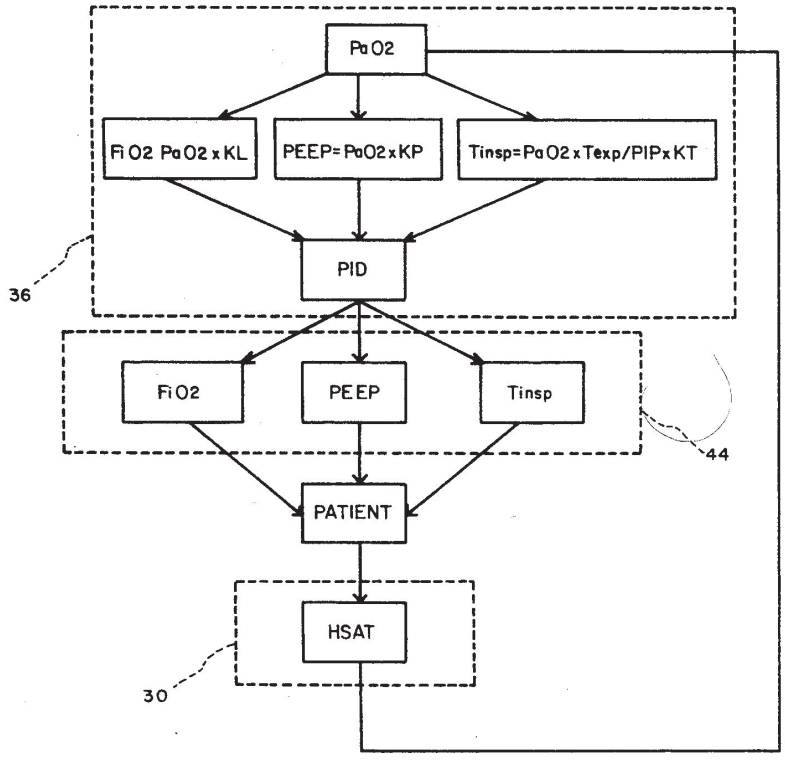
Diane Blodgett, *Manual of Respiratory Care Procedures* (Philadelphia:Lippencott, 1987) pp. 204–205.

Primary Examiner—Edgar S. Burr
Assistant Examiner—Eric P. Raciti
Attorney, Agent, or Firm—John G. Mills & Associates

[57] **ABSTRACT**

An automatic controller utilizes a pulse oximeter signal to regulate the oxygen mixture output, peak expiratory end pressure, and inspiratory ventilation time from a positive pressure respiratory assist ventilator. The pulse oximeter senses a patient's hemoglobin saturation and pulse rate by an optical sensor to develop a signal which is used by calculator to determine the patient's corresponding partial pressure of arterial blood. The calculated partial pressure of arterial blood is then used by the calculator in determining the level of inspired oxygen, peak expiratory end pressure, and inspiratory ventilation time provided to the patient. The calculator generates a signal to control the level of inspired oxygen, expiratory end pressure, and inspiratory ventilation time output from a positive pressure respiratory assist ventilator. The level of inspired oxygen, peak expiratory end pressure, and inspiratory ventilation time provided from the ventilator to the patient is varied to maintain a desired predetermined partial pressure of arterial oxygen.

1 Claim, 3 Drawing Sheets



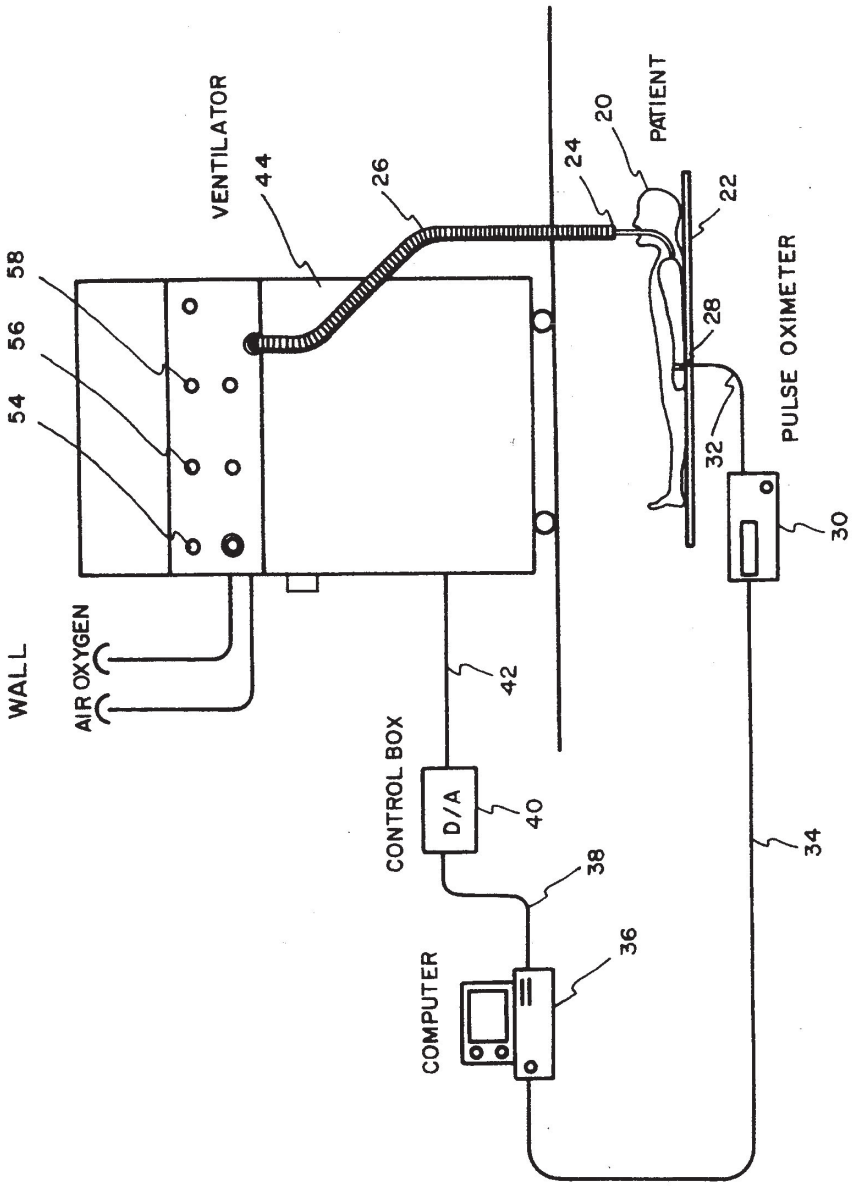

VENTILATOR
44
26
24
20
PATIENT
22
58
56
54
28
PULSE OXIMETER
32
30
WALL
AIR OXYGEN
42
CONTROL BOX
D/A
40
38
34
36
COMPUTER

FIG. 1

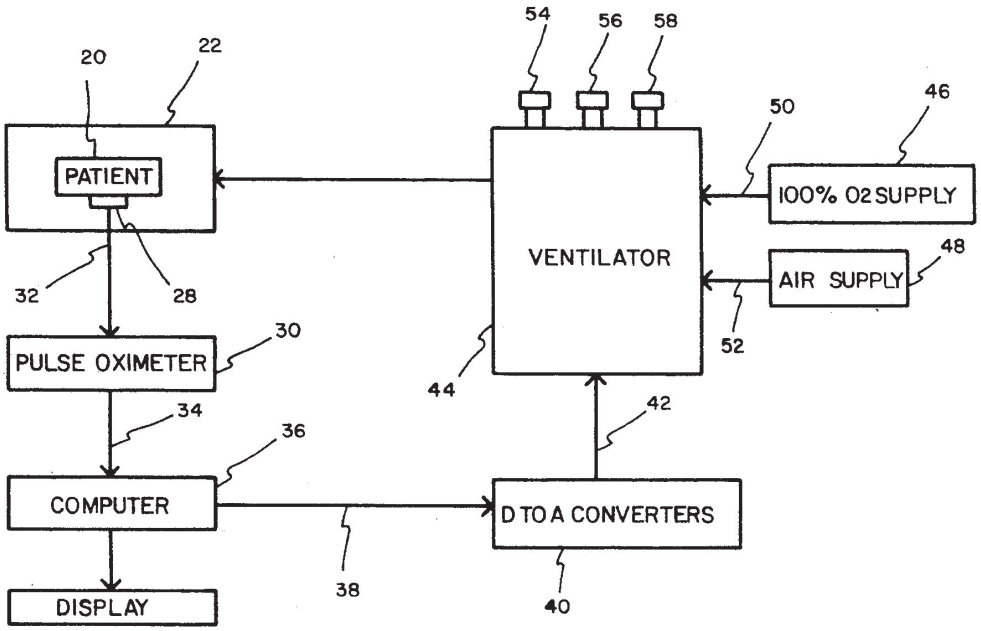

54
56
58
20
22
46
50
PATIENT
100% O2 SUPPLY
VENTILATOR
AIR SUPPLY
48
32
28
52
PULSE OXIMETER
30
44
42
34
36
COMPUTER
D TO A CONVERTERS
38
40
DISPLAY

FIG. 2

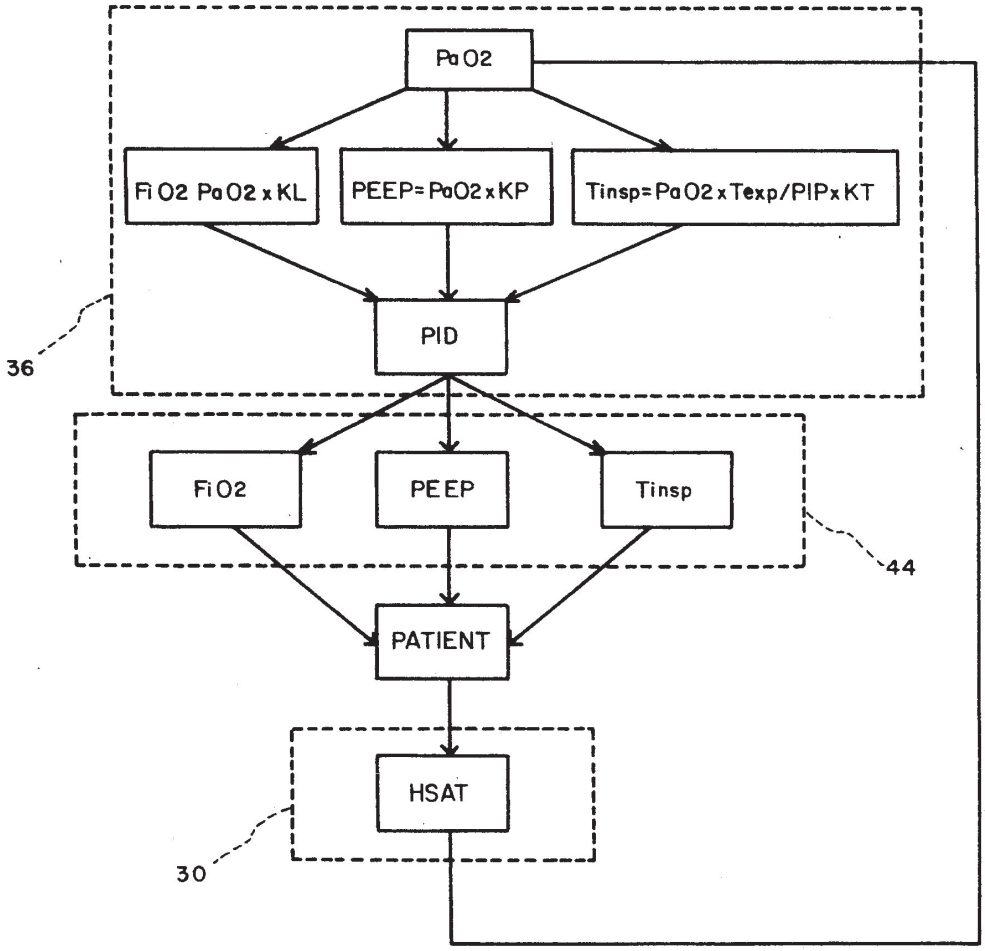

PaO2
FiO2 PaO2 x KL
PEEP=PaO2 x KP
Tinsp=PaO2 x Texp/PIP x KT
PID
36
FiO2
PEEP
Tinsp
44
PATIENT
HSAT
30

FIG. 3

ADAPTIVE CONTROLLER FOR AUTOMATIC VENTILATORS

FIELD OF INVENTION

This invention relates to positive pressure ventilation systems and more particularly to automatic controls for the same.

BACKGROUND OF INVENTION

Devices for controlling oxygen content of blood by controlling breathing parameters such as inspiratory time, peak expiratory end pressure, and expired oxygen delivery to the patient are well known. Details of these various systems will be hereinafter discussed in detail in the description of the prior art. None of the prior art, however, utilizes sensed hemoglobin saturation to concurrently and adaptively control the FiO_2 inspiratory time, and the expiratory end pressure of breathing air from a ventilator supplying pulsed positive pressure breathing air to a patient.

BRIEF DESCRIPTION OF INVENTION

This invention relates to positive pressure ventilation assist respirator systems. The system has particular application in the adaptive control of the inspiratory ventilation time (Tinsp), peak expiratory end pressure (PEEP), and fraction in inspired oxygen (FiO_2) and is intended to make more automatic the control of the above patient parameters.

This system utilizes a pulse oximeter to optically determine hemoglobin saturation (HSAT) of the patient's blood, linear interpolate the HSAT to calculate the partial pressure of arterial oxygen (PaO_2), and use this information to regulate the length of inspiration time (tinsp), PEEP, and FiO_2 to a patient's breathing tube. The control mechanism is derived from the known relationship between the preset level of Tinsp, PEEP, minimum required FiO_2 delivered to the patient, and predetermined lung function dynamics in order to maintain a desirable PaO_2.

DISCUSSION OF PRIOR ART

The following references represent the closest prior art of which the inventor is aware and is intended to meet the requirements for Information Disclosure Statements.

List of References:

U.S. Pat. No. 2,414,747 Issue Date: Jan. 21, 1947 Inventor: Harry Kirschbaum

U.S. Pat. No. 3,734,091 Issue Date: May 22, 1973 Inventor: Ronald H. Taplin

U.S. Pat. No. 4,326,513 Issue Date: Apr. 27, 1982 Inventor: Volker Schultz et al

U.S. Pat. No. 4,889,116 Issue Date: Dec. 26, 1989 Inventor: 4,889,116

U.S. Pat. No. 5,103,814 Issue Date: Apr. 14, 1992 Inventor: Timothy Maher

CONCISE EXPLANATION OF REFERENCES

Devices for controlling the oxygen content of blood by controlling breathing parameters such as inspiratory time, peak expiratory end pressure, and inspired oxygen delivery to a patient are well known. U.S. Pat. No. 2,414,747 issued to Harry Kirschbaum on Jan. 21, 1947 shows a method and apparatus for controlling the oxygen content of the blood of living animals which discloses control of blood oxygen content by the use of an ear oximeter which produces a signal used to control the proportion of inspired oxygen. By directing a beam of light through a capillary bed, as in the ear, the characteristics of the light become modified by the color of the blood that intercepts its path. Thus, the change in oxygen levels of the blood can be detected non-invasively where signals can be generated, amplified and used to control the oxygen supply delivered to a patient. Numerous improvements have been made since that time wherein better matching of oxygen delivery to the needs of the patient have been made such as shown in U.S. Pat. No. 3,734,091 to Ronald H. Taplin issued on May 22, 1973. Taplin discloses an optical oximeter and a temporary oxygen deficient mixture (anoxic) to control blood saturation. Thus, to prevent super saturation, or more than a 100% oxygen saturation, Taplin discloses limiting the oxygen by providing the anoxic mixture each time the saturation of the blood reaches a predetermined percentage level.

An invasive patient data controlled respiration system is shown in U.S. Pat. No. 4,326,513 to Volker Schultz et al issued on Apr. 27, 1982 which shows a patient data controlled respiration system utilizing sensed concentration of oxygen in the patient's blood to control a respirator supplying breathing air having the selected concentration of oxygen to the patient. In such a system, a sensor is connected to the patient for sensing arterial partial pressure of the patient's blood (PaO_2). The system further includes a minimizing comparator which has preset threshold levels and determines whether the FiO_2 value is above or below those threshold values. When a transient FiO_2 value rises above or drops below the threshold value, it causes the control devise to cancel the adjustment to the inspired oxygen and causes the previous amount of oxygen to be supplied to the patient. In this way, there can be only small changes in the original FiO_2.

An adaptive oxygen controller utilizing a pulse oximeter for measuring a patient's blood hemoglobin saturation (HSAT) and pulse rate is shown in U.S. Pat. No. 4,889,116 to John C. Taube, issued on Dec. 26, 1989 which shows an oxygen blending system utilizing a patient's sensed hemoglobin saturation to adaptively control the output of an oxygen blender supplying breathing air to the patient. In such a system, the sensed hemoglobin saturation via a pulse oximeter is utilized by the system to adaptively adjust the FiO_2 delivered to a breathing mask or hood. In this way, small adjustments in FiO_2 minimize the change in a patient's HSAT level.

A self compensating respirator utilizing a pulse oximeter and device for measuring a patient's expired breathing air carbon dioxide (CO_2) level is shown in U.S. Pat. No. 5,103,814 to Timothy Maher, issued on Apr. 14, 1992 which shows a respirator system utilizing a patient's sensed HSAT and CO_2 to control a ventilator FiO_2 and breathing air rate to the patient. In such a system, the sensed HSAT via a pulse oximeter is utilized by the system to periodically decrease the oxygen level delivered to a patient's breathing tube. The system also utilizes sensed CO_2 to periodically decrease the rate of the respirator delivering breathing air to the patient. In this way, both FiO_2 and rate are systematically decreased 1o progressively wean the patient from mechanical ventilation.

The prior art is however, devoid of a system which utilizes sensed hemoglobin saturation to concurrently

and adaptively control the FiO_2, inspiratory time, and peak expiratory end pressure of breathing air from a ventilator supplying pulsed positive pressure breathing air to a patient. The adaptive control of FiO_2, inspiratory time, and peak expiratory end pressure is vital for the patient's changing need for increasing and decreasing of blood oxygenation.

OBJECTS OF THE INVENTION

It is therefore an object of the invention to provide a new and useful adaptive control of inspiratory ventilation time, peak expiratory end pressure, and fraction of inspired oxygen.

Another object of the invention is to provide a new and improved respiration system which automatically provides the highest oxygen saturation in the blood while maintaining the highest possible inspiratory ventilation time of oxygen delivered to the patient.

Another object of the invention is to provide a new and improved respiration system which automatically provides the highest oxygen saturation in the blood while maintaining the lowest possible peak expiratory end pressure of oxygen delivered to the patient.

Yet another object of the invention is to provide a new and improved respiration system which automatically provides the highest oxygen saturation in the blood while maintaining the lowest possible fraction of inspired oxygen delivered to the patient.

These and other objects of the invention are achieved by providing an adaptive controller for the adjustment of inspiratory time of oxygen, peak expiratory end pressure of oxygen, and fraction of positive pressure inspired oxygen delivered to a patient. The controller comprises an oximeter connected by an optical sensor to the patient for measuring the patient's blood hemoglobin saturation and pulse rate. The oximeter generates signals representative of the blood hemoglobin saturation and pulse rate. Calculation means are provided which axe responsive to the signals from the oximeter for determining the inspiratory time of oxygen, peak expiratory end pressure, and fraction of positive pressure inspired oxygen delivered to the patient. A source of oxygen and a source of air are provided for combining or mixing, and pressurization of the gases and inspiratory administration to the patient. The means for controlling the gas mixture, pressure, and inspiratory administration time is controlled by calculation means to provide a calculated percentage of oxygen, peak expiratory end pressure, and inspiratory time and has an output connected to the patient so that the gas taken in by the patient automatically causes the blood in the patient to reach a predetermined hemoglobin saturation level which adapts to the patient's respiratory requirements.

Other objects and advantages of the present invention will become apparent and obvious from a study of the following description and the accompanying drawings which are merely illustrative of such invention.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1** is diagrammatic view of the automatic ventilator control system of the present invention;

FIG. **2** is a schematic of the diagram of the same; and

FIG. **3** is a flow diagram showing the operation of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, an automatic controller of ventilator oxygen is shown in FIG. **1** for the purpose of providing positive pressure inspired oxygen with a peak expiratory end pressure and with an inspiratory ventilation time to a patient **20**. The patient **20** is shown lying on a mattress **22** having a breathing tube inserted through the mouth and trachea.

The breathing tube controls the breathing environment of the patient and is connected to connective tubing **26** which delivers positive pressure oxygen to the patient.

An optical sensor **28** is placed on the patient's finger. The system also includes a pulse oximeter **30** of the type made by Nellcor Incorporated, of Haywood, Calif. which is shown in U.S. Pat. No. 4,653,498 issued Mar. 31, 1987. Pulse oximeter **30** is connected by a cable **32** to the sensor **28**.

The pulse oximeter is connected via a cable **34** to a computer **36**. The computer's outputs are connected via cable **38** and then via digital/analog converter **40** and then via lines **42** to a ventilator **44**.

The connections of the various components of this system are best understood in connection with the schematic block diagram shown in FIG. **2**.

As seen in FIG. **2**, the sensor **28** is attached to patient **20** and is connected by the cable **32** to pulse oximeter **30**. The pulse oximeter **30** determines from the optical sensing of the patient the pulse strength, hemoglobin saturation, and pulse rate. The values of all three of these parameters are digitally displayed on the front of the face of the pulse oximeter in digital form by suitable displays (not shown). The pulse oximeter **30** transfers in digital form over a cable **34** to the computer **36** the digital representations of the pulse strength, hemoglobin saturation (HSAT), and pulse rate. The computer **36** utilizes the hemoglobin saturation which is provided in digital form on lines **34** for determining the partial pressure of arterial oxygen (PaO_2) and thus the appropriate level of inspiratory ventilation time (Tinsp), peak expiratory end pressure (PEEP) of ventilation, and fraction of positive pressure inspired oxygen (FiO_2) to provide to the patient to produce the highest obtainable patient arterial blood oxygen level with a minimum of oxygen necessary to be added to the air supply having a 21% oxygen concentration.

The signals representative of the appropriate Tinsp, PEEP, and FiO_2 are provided in digital form via lines **38** to a digital to analog converter **40**. The digital to analog converter provides the signals to the ventilator via lines **42**, which controls the inspiratory ventilation time, peak expiratory end pressure of ventilation, and fraction of positive pressure inspired oxygen supplied to the patient. A pure oxygen supply source **45** and air supply **48** containing 21% oxygen concentration are both provided which are connected via tubes **50** and **52**, respectively, to the ventilator **44**. Conventional solenoid control is used for the purpose of making proportional the Tinsp, PEEP, and FiO_2 in accordance with the signals provided by lines **42** from the digital to analog converter. Accordingly, the appropriate fraction of positive pressure inspired oxygen at an appropriate inspiratory ventilation time and peak expiratory end pressure is provided to the breathing tube **24** via tube **26**

to the patient. The ventilator **44** also has attached thereto three manual knobs **54**, **55**, and **56** which are connected to the oxygen supply solenoid, expiratory resistance solenoid, and the inspiratory time solenoid, respectively. The knobs enable manual regulation by physician or operator to provide an appropriate Tinsp, PEEP, and FiO_2 to the patient.

The computer is controlled by program modules to determine Tinsp, PEEP, and FiO_2. The flow chart used for determining the roper Tinsp, PEEP and FiO_2 to provided to the patient is shown in FIG. **3**.

Referring to FIG. **3**, the TinSD, PEEP, and FiO control program flow diagram is shown. Accordingly, the description of the operation of the Tinsp, PEEP, and FiO_2 control program is as follows:

1. The computer receives an HSAT signal from the pulse oximeter and calculates a PaO_2 value for the patient.
2. The computer then determines modification values of Tinsp, PEEP, and FiO_2 from the calculated PaO_2.
3. The computer then determines the proportional, differential, and integral gain coefficients to develop control signals to the ventilator.
4. The computer then sends control signals to the ventilator for the modification of Tinsp, PEEP, and FiO_2 values.
5. The patient then breaths in through a breathing tube the positive pressure air at the modified Tinsp, PEEP, and FiO_2 values. The values of Tinsp, PEEP, and FiO_2 are chosen by the computer to maintain a desired level of the patient's blood oxygen level.
6. The pulse oximeter via an optical sensor connected to the patient calculates the patient's hemoglobin saturation (HSAT). An HSAT signal representing the patient's blood oxygen level is then generated by the pulse oximeter and transmitted to the computer.

In the overall operation of the system, the pulse oximeter and the ventilator **44** as well as the computer **36** are connected as shown in FIG. **1** to the patient. The pulse oximeter **30** is turned on and the patient's hemoglobin saturation (HSAT) is monitored by the attending physician. The positive pressure oxygen percentage (FiO_2), peak expiratory end pressure (PEEP), and inspiratory time (Tinsp) are manually controlled by knobs **54**, **55**, and **56** which are part of manually controlled valves provided on the ventilator **44**. The knobs are adjusted until the physician can obtain the highest level of HSAT in the patient's blood level while using the most minimum level of FIO_2, minimum level of PEEP, and maximum level of Tinsp for the patient.

The FiO_2, PEEP, and Tinsp levels are then controlled automatically by the patient's hemoglobin saturation signals from the pulse oximeter **30**.

It can therefore be seen that a new and improved adaptive control system for a fraction of inspared oxygen, peak expiratory end pressure, and inspiratory time has been provided.

The system takes advantage of the unique ability of a pulse oximeter to accurately determine peak arterial oxygen levels. This enables the control system to accurately derive a fraction of inspired oxygen level, peak expiratory end pressure, and inspiratory time which better matches the needs of the patient.

The present invention may, of course, be carried out in other specific ways than those herein set forth without departing from the spirit and essential characteristics of such invention. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

What is claimed is:

1. A pulsed positive pressure ventilation assist respirator system comprising:

a ventilator means for providing a selected level of positive pressure respirable gas, said ventilator means further having register means for providing a predetermined level of patient parameters to said ventilator, said patient parameters consisting in inspiration time (T_{insp}), positive end expiratory pressure (PEEP) and minimum required fraction inspired oxygen (FiO_2);

pulse oximeter means for optically determining the hemoglobin saturation (HSAT) of the patient's blood;

interpolation means for linearly interpolating the HSAT value provided by said pulse oximeter means for calculating the partial pressure of arterial oxygen (PaO_2) of a patient;

a control mechanism comprising calculation means for deriving a relationship between said patient parameters in said register means and HSAT value provided by said pulse oximeter means; said control mechanism further comprising adaptive means for providing said register means with updated adjusting values for said patient parameters for maintaining a predetermined PaO_2.

* * * * *