US 20090007918A1

(19) **United States**

(12) **Patent Application Publication**

Darkin et al.

(10) **Pub. No.: US 2009/0007918 A1**

(43) **Pub. Date: Jan. 8, 2009**

(54) **METHOD AND APPARATUS FOR MONITORING THE CONDITION OF A PATIENT WITH DIABETES**

(75) Inventors: **Donald Darkin**, Kenthurst (AU); **Klaus Henry Schindhelm**, Glenhaven (AU); **Carmel Therese Harrington**, Coogee (AU)

Correspondence Address:
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203 (US)

(73) Assignee: **ResMed Limited**, Bella Vista (AU)

(21) Appl. No.: **11/997,976**

(22) PCT Filed: **Feb. 16, 2007**

(86) PCT No.: **PCT/AU2007/000172**

§ 371 (c)(1),
(2), (4) Date: **Feb. 5, 2008**

(30) **Foreign Application Priority Data**

Feb. 17, 2006 (AU) 2006900780

Publication Classification

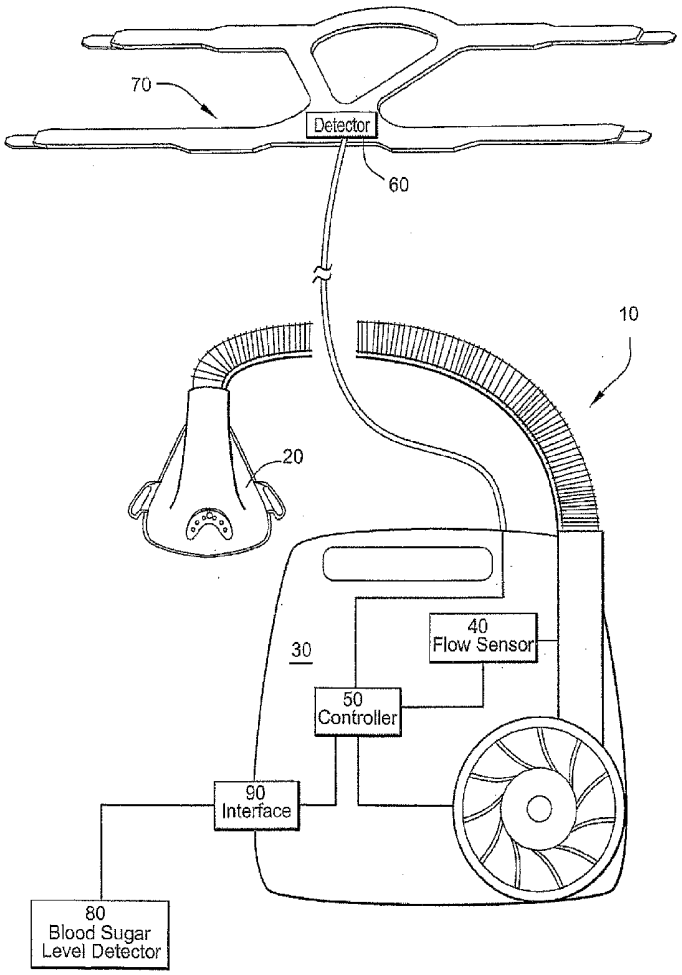
(51) **Int. Cl.**

A61M 16/10	(2006.01)
A61B 5/00	(2006.01)
A61B 5/01	(2006.01)
A61B 5/024	(2006.01)
A61B 5/08	(2006.01)
A61B 5/145	(2006.01)
A61M 37/00	(2006.01)

(52) **U.S. Cl.** **128/205.25**; 600/306; 600/549; 600/508; 600/529; 600/365; 604/66

(57) **ABSTRACT**

According to certain example embodiments of this invention, there is provided an apparatus for treatment of a patient with both sleep-disordered breathing and diabetes. A PAP device may be configured to provide a supply of pressurized breathable gas. At least one glycemia sensor also may be provided. A controller may be operable to receive a signal from the at least one glycemia detector and may be further operable to analyze the signal for an indication of a glycemia abnormality (e.g., hypoglycemia, hyperglycemia, diabetic coma, etc.). Optionally, when the signal indicates that the patient is experiencing a diabetic event, an alert may be generated and/or a drug delivery unit may administer an appropriate treatment to the patient.



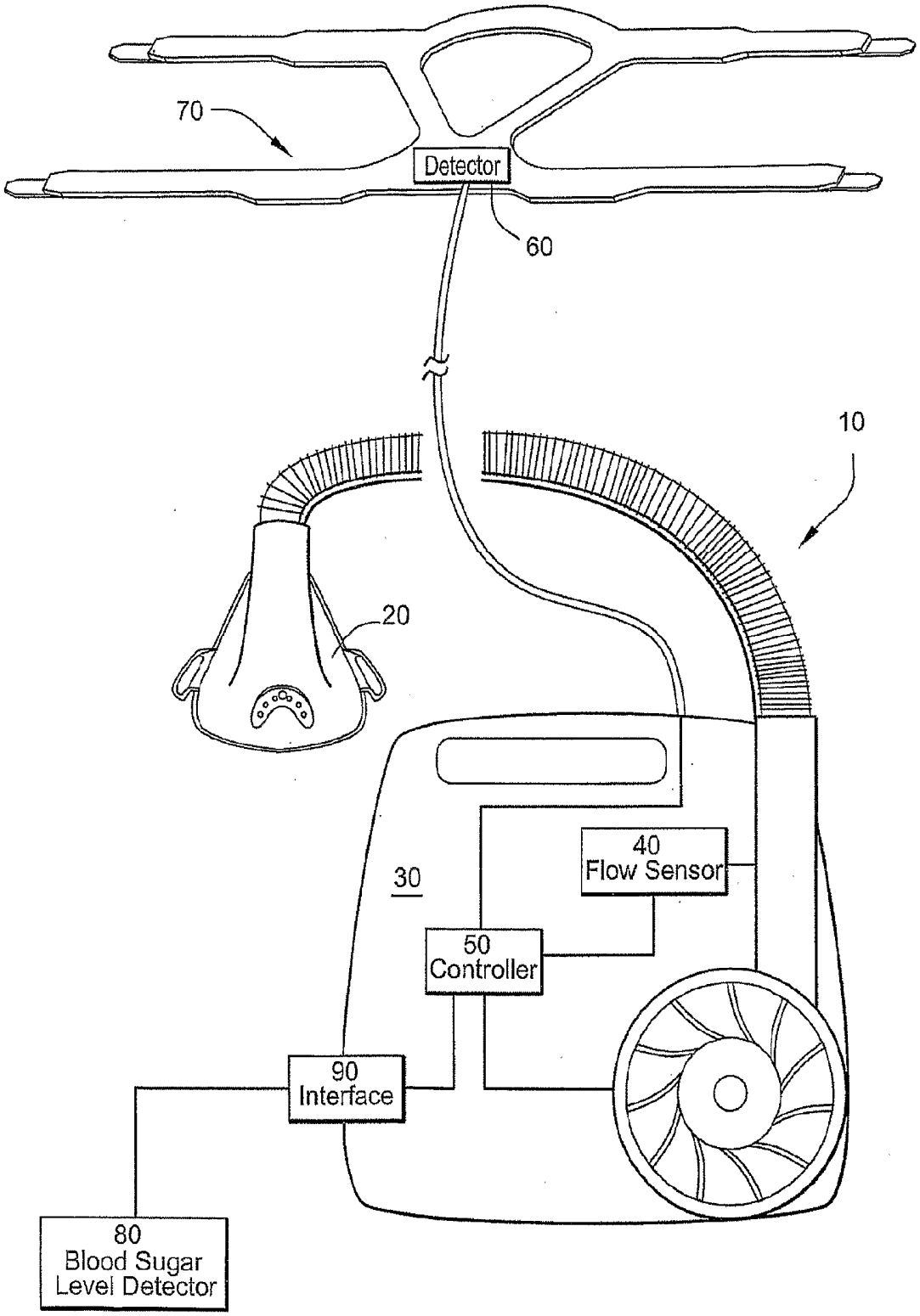

70
Detector
60
10
20
30
40
Flow Sensor
50
Controller
90
Interface
80
Blood Sugar
Level Detector

FIG. 1

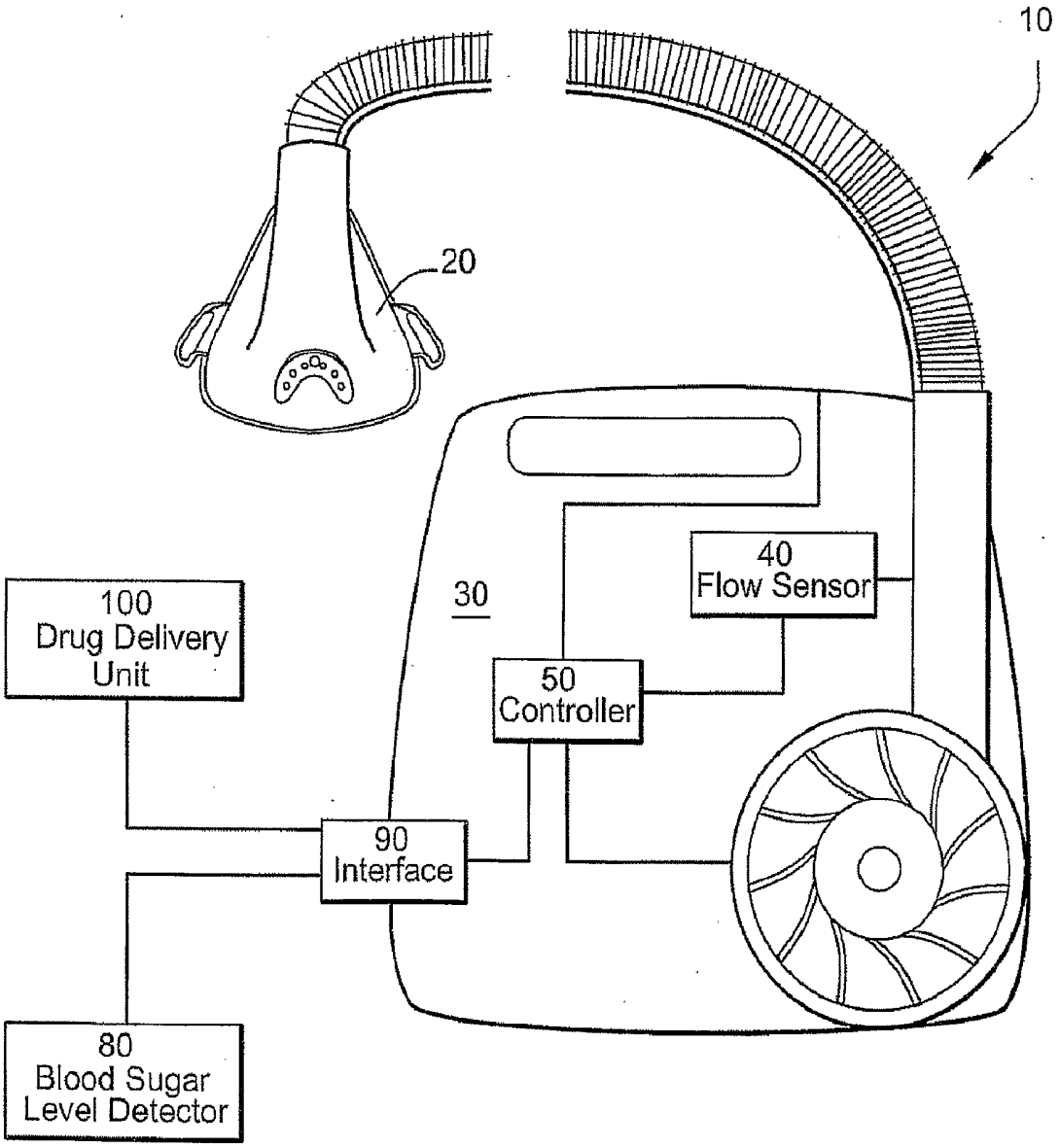

10
20
30
40
Flow Sensor
50
Controller
100
Drug Delivery
Unit
90
Interface
80
Blood Sugar
Level Detector

FIG. 2

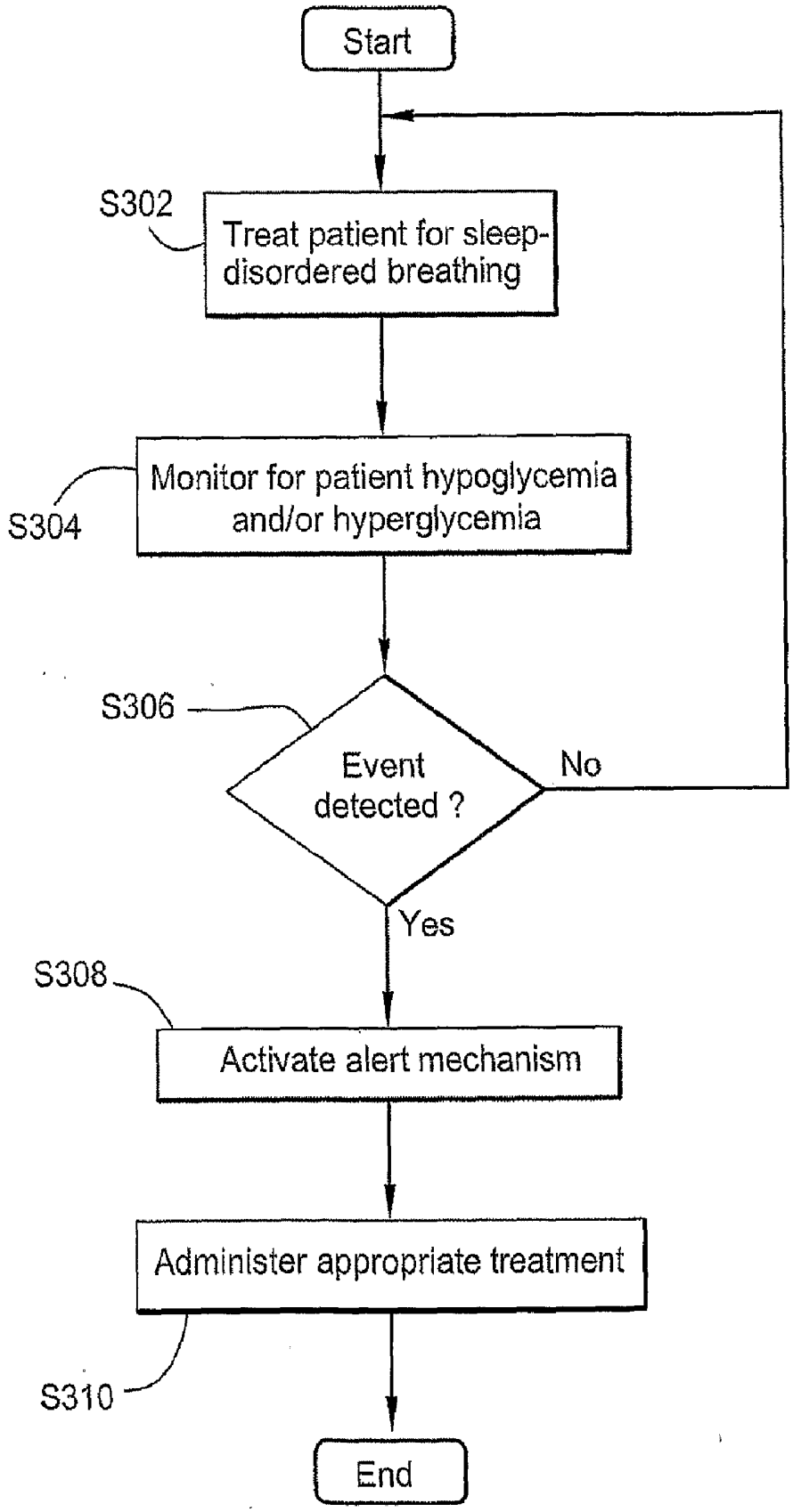

Start
S302
Treat patient for sleep-disordered breathing
Monitor for patient hypoglycemia and/or hyperglycemia
S304
S306
Event detected ?
No
Yes
S308
Activate alert mechanism
Administer appropriate treatment
S310
End

FIG. 3

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of Australian Patent Application No. 2006 900780, filed Feb. 17, 2006, incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] Certain example embodiments described herein relate to the monitoring of diabetic patients and, more particularly, certain example embodiments described herein relate to monitoring diabetic patients during sleep.

BACKGROUND OF THE INVENTION

[0003] Sleep-Disordered Breathing (SDB) is a general term for a sleep disorder with apneas and hypopneas. Obstructive Sleep Apnea (OSA) is an example of such a sleep disorder. Sullivan invented treatment of OSA with nasal Continuous Positive Airway Pressure (CPAP). See U.S. Pat. No. 4,944,310 (Sullivan). An apparatus for CPAP treatment typically includes: (i) a source of air at positive pressure, such as a blower, flow generator, or other positive airway pressure (PAP) device; (ii) an air delivery conduit; and (iii) a patient interface, such as a mask. The patient interface typically is connected to the patient with headgear including, for example, a series of elastic straps. At least a portion of the headgear is in contact with the patient's skin, typically on the patient's face. Patients wear the apparatus while sleeping.

[0004] A basic CPAP device may provide a supply of air at a generally fixed pressure in the range of 4-20 cmH_2O. A more advanced CPAP device such as ResMed's AUTOSET SPIRIT can monitor the patient's breathing, determine the shape of the breath waveform, detect the presence of snoring, apneas, and hypopneas, and also adjust the treatment pressure. See U.S. Pat. No. 5,704,345 (Berthon-Jones), the entire contents of which is incorporated herein by reference.

[0005] Diabetes is a disease characterized by an elevated level of glucose in the blood and in the urine. When blood sugar extremes—both high (hyperglycemia) and low (hypoglycemia)—are not treated, a patient can fall into a diabetic coma. The most common cause of diabetic coma is hypoglycemia. This is caused by excessive treatment with insulin relative to food intake and physical activity. Research indicates that the frequency of severe hypoglycemia is about 1.9 and 2.6 episodes per patient per year for Type 1 and Type 2 diabetes patients, respectively, with approximately 50% of these episodes occurring during sleep. There is evidence that the fear of a hypoglycemic episode significantly affects patient outcomes, such as glycemic control and management, self-treatment modifications, and post-episode lifestyle infringements (see Leiter et al. 2005, *Canadian J Diabetes;* 29:186-192). Recent studies have indicated that about 30% of diabetic patients also have OSA (Meslier et al, *Eur. Resp. J,* 22(1):156-160), and there is emerging data indicating that effective treatment of OSA with n-CPAP significantly improves glucose metabolism.

[0006] Given that many diabetic patients will require treatment for their OSA or other SDB, certain example embodiments of the present invention are directed towards improving patient outcomes by providing methods and apparatuses that can reduce the patients' fear of hypoglycemia and/or other diabetes-related events.

SUMMARY OF THE INVENTION

[0007] One aspect of certain example embodiments of the invention is to provide an apparatus comprising a hypoglycemia detector and an action unit. In one form, the hypoglycemia detector monitors for one or more of the following: shallow patient breathing, rapid heart rate, temperature, and sweating and, when it detects conditions indicative of hypoglycemia, it sends a signal to the action unit. In one form, the action unit generates a local and/or external alarm upon receipt of a signal from the detector.

[0008] According to certain example embodiments, an apparatus for treatment of a patient with both sleep-disordered breathing and diabetes is provided. Such an apparatus may comprise a blower configured to provide a supply of air at positive pressure; a patient interface; headgear to hold the patient interface in position in communication with a patient's airways; at least one hypoglycemia sensor; and an alarm. A controller also may be provided, with the controller being programmed to receive a signal from the at least one hypoglycemia detector, analyze the signal for indications of hypoglycemia, and upon detection of an indication of hypoglycemia trigger the alarm.

[0009] According to certain other example embodiments, an apparatus for treatment of a patient with both sleep-disordered breathing and diabetes is provided. A positive airway pressure (PAP) device configured to provide a supply of pressurized breathable gas is provided. At least one glycemia sensor also is provided. A controller is operable to receive a signal from the at least one glycemia detector and is further operable to analyze the signal for an indication of a glycemia abnormality (e.g., hypoglycemia, hyperglycemia, diabetic coma, etc.).

[0010] According to still other embodiments, a method of treating a patient with both sleep-disordered breathing and diabetes is provided. A supply of pressurized breathable gas is provided to the patient. A signal indicative of whether the patient is experiencing a diabetic event is generated. Optionally, when the signal indicates that the patient is experiencing a diabetic event, an alert mechanism may be activated and/or a corresponding treatment may be administered.

[0011] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0013] FIG. **1** is an apparatus including a positive airway pressure (PAP) device, patient interface, headgear, and glucose sensor, in accordance with an example embodiment;

[0014] FIG. **2** is an apparatus for treating a patient with both sleep-disordered breathing and diabetes, in accordance with another example embodiment; and,

[0015] FIG. **3** is an illustrative flowchart showing a procedure for treating a patient with both sleep-disordered breathing and diabetes.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0016] In one example embodiment an apparatus **10** includes a patient interface—for example, a nasal mask **20**—connected to a positive airway pressure (PAP) device **30** including a flow sensor **40**. Patient breathing in the nasal mask **20** is detected by the flow sensor **40**, which generates a flow signal that is sent to the controller **50**. The controller **50** includes a microprocessor or any suitable combination of hardware, software, or other programmed logic circuitry operable to analyze signals from a range of inputs. In the controller **50**, components of the flow signal caused by leak may be filtered (e.g., reduced and/or removed), thereby providing a respiratory flow signal. The heart rate is detected from small oscillations in the flow signal occurring in a frequency band around 1 Hz. Ventilation is determined from the respiratory flow signal.

[0017] In certain example embodiments, the apparatus **10** may include a detector **60** built into the headgear **70**. In certain example embodiments, the headgear **70** may further comprise skin conductivity sensors in one or more locations in the headgear **70**. Such skin conductivity sensors may be arranged so as to be in contact with the skin. Patient sweating can be detected as a change in skin conductivity. In certain example embodiments, the headgear **70** may further include skin temperature sensors. More generally, in certain example embodiments, sensors may be built into and/or otherwise connected to the headgear **70** to detect indications of sympathetic nervous system activation. See, for example, U.S. Publication No. 2006/0100538, the entire contents of which are incorporated herein by reference.

[0018] In certain example embodiments, a hypoglycemic detector may be provided, which may include a transcutaneous blood sugar level detector **80** connected to the controller **50** via an interface **90**. In certain example embodiments, the blood sugar level detector **80** may include a sensor on a nasal prong for contact with the mucosal regions of the nares. In certain other example embodiments, the sensor may be suitable to be used on a limb of a patient, such as an arm.

[0019] In certain example embodiments, the hypoglycemic detector may measure the glucose level in a small amount of interstitial fluid that has been removed from between the skin cells by a vacuum action.

[0020] In certain example embodiments, the hypoglycemic detector may use a plethysmogram to detect a range of patient parameters including heart rate. See, for example, PCT Patent Application No. PCT/AU2005/001543 (Martin & Oates), the entire contents of which is hereby incorporated herein by reference.

[0021] In certain example embodiments, the hypoglycemic detector may use an electroencephalogram (EEG) to determine when a patient is in a coma. The EEG sensors may be built into the headgear, for example, by using a device manufactured by Advanced Brain Monitoring, Inc.

[0022] In certain example embodiments, an action unit is provided, which includes a buzzer that generates an audible signal when hypoglycemia is detected by the detector. In certain other example embodiments, the action unit is connected to a remote monitoring station via a network (e.g., the Internet, a LAN, a WAN, etc.). When hypoglycemia is detected, the action unit may send a signal to the remote monitoring station to indicate that the patient is potentially suffering from a diabetic coma. It will be appreciated that the alarm may include one or more of an audible and/or visual alert, a remote notification, an automated delivery of a treatment (e.g., insulin), etc.

[0023] In certain example embodiments, the action unit may further include a drug delivery unit that can supply glucose or insulin, as appropriate, to the person. For example, patients suffering from hypoglycemia may be given glucose, hyperglycemic patients may receive oral insulin via the mask, etc.

[0024] Similar to FIG. **1**, FIG. **2** is an apparatus for treating a patient with both sleep-disordered breathing and diabetes, in accordance with another example embodiment. As shown in FIG. **2**, a drug delivery unit **100** may be provided to the apparatus which is shown without the headgear **70**. Based on the signals at one or more of the flow sensor **40**, the blood sugar level detector **80**, etc., the controller **50** may determine that a diabetic event (e.g., hypoglycemia, hyperglycemia, diabetic coma, etc.), apnea or hypopnea event, and/or other events has/have occurred. In response, the controller **50** may, via the interface **40**, instruct the drug delivery unit **100** to supply a treatment to the patient. For example, oral insulin, glucose, etc. may be administered automatically (e.g., via a vapor and/or aerosol delivery) and/or recommended for administration by a human user.

[0025] FIG. **3** is an illustrative flowchart showing a procedure for treating a patient with both sleep-disordered breathing and diabetes. In FIG. **3**, a patient is treated for sleep-disordered breathing in step S**302**. Monitoring for hypoglycemia and/or hyperglycemia is performed in step S**304**. The monitoring process may include gathering relevant signals (e.g., patient sweat, heart rate, EEG signals, breath, snore, blood sugar level, etc.) and/or filtering such signals when necessary. If a diabetic event is not detected in step S**306**, the normal treatment and monitoring continues. However, if a diabetic event is detected in step S**306**, an alert mechanism is activated in step S**308**. As noted above, the alert mechanism may include, for example, activating an audio/visual alarm, notifying a monitoring station that may be located remote from the patient, etc. Additionally, an appropriate treatment may be administered in step S**310**.

[0026] Given these techniques, patients suffering from both OSA and/or other sleep-disordered breathing and diabetes who are being treated with nasal CPAP can sleep with the assurance that should they begin to become hypoglycemic, their CPAP device will detect this and raise an alarm and/or take a suitable counteraction.

[0027] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments.

[0028] Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodi-

ments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

1. An apparatus for treatment of a patient with both sleep-disordered breathing and diabetes comprising:
- a blower configured to provide a supply of air at positive pressure;
- a patient interface;
- headgear to hold the patient interface in position in communication with a patient's airways;
- at least one hypoglycemia sensor;
- an alarm; and
- a controller,
- wherein the controller is programmed to receive a signal from the at least one hypoglycemia detector, analyze the signal for indications of hypoglycemia and upon detection of an indication of hypoglycemia trigger the alarm.

2. The apparatus according to claim **1**, wherein said at least one hypoglycemia detector detects activation of the sympathetic nervous system.

3. The apparatus according to claim **1**, wherein said at least one hypoglycemia detector detects at least one of: patient sweating, temperature, heart rate, and respiration rate.

4. The apparatus according to claim **1**, further comprising a flow sensor in fluid communication with the patient interface.

5. The apparatus according to claim **1**, wherein said alarm is a buzzer.

6. The apparatus according to claim **1** wherein said alarm is sent to a remote monitoring system.

7. An apparatus for treatment of a patient with both sleep-disordered breathing and diabetes comprising:
- a PAP device configured to provide a supply of pressurized breathable gas;
- at least one glycemia sensor; and,
- a controller operable to receive a signal from the at least one glycemia detector and further operable to analyze the signal for an indication of a glycemia abnormality.

8. The apparatus according to claim **7**, wherein the at least one glycemia sensor is one or more of: a transcutaneous blood sugar level detector, a sensor for contact with mucosal regions of the patient nares on a nasal prong of a mask connected to the PAP device, and a sensor capable of measuring the patient's glucose level by extracting a small amount of interstitial fluid that has been removed from between the skin cells via a vacuum tube.

9. The apparatus according to claim **8**, wherein said at least one glycemia detector detects activation of the sympathetic nervous system.

10. The apparatus according to claim **7**, wherein said at least one glycemia detector detects at least one of: patient sweating, temperature, heart rate, and respiration rate.

11. The apparatus according to claim **7**, wherein the controller is further operable to sound an audible alert when the signal indicates a glycemia abnormality.

12. The apparatus according to claim **7**, wherein the controller is further operable to send information about the patient treatment to a remote monitoring station.

13. The apparatus according to claim **12**, wherein the controller is configured to send the information when the signal indicates one or more of: patient hypoglycemia, hyperglycemia, and/or diabetic coma.

14. The apparatus according to claim **7**, further comprising a drug delivery unit.

15. The apparatus according to claim **14**, wherein the drug delivery unit is configured to supply glucose and/or insulin to the patient.

16. A method of treating a patient with both sleep-disordered breathing and diabetes, the method comprising:
- providing a supply of pressurized breathable gas to the patient; and,
- generating a signal indicative of whether the patient is experiencing a diabetic event.

17. The method according to claim **16**, further comprising when the signal indicates that the patient is experiencing a diabetic event, activating an alert mechanism.

18. The method according to claim **17**, wherein the step of activating the alert mechanism is further practiced by sounding an audible alarm.

19. The method according to claim **17**, wherein the step of activating the alert mechanism is further practiced by notifying a remote monitoring station.

20. The method according to claim **16**, further comprising when the signal indicates that the patient is experiencing a diabetic event, administering a corresponding treatment.

* * * * *

专利名称(译)	用于监测患有糖尿病的患者状况的方法和装置		
公开(公告)号	US20090007918A1	公开(公告)日	2009-01-08
申请号	US11/997976	申请日	2007-02-16
[标]申请(专利权)人(译)	雷斯梅德有限公司		
申请(专利权)人(译)	瑞思迈有限公司		
当前申请(专利权)人(译)	瑞思迈有限公司		
[标]发明人	DARKIN DONALD SCHINDHELM KLAUS HENRY HARRINGTON CARMEL THERESE		
发明人	DARKIN, DONALD SCHINDHELM, KLAUS HENRY HARRINGTON, CARMEL THERESE		
IPC分类号	A61M16/10 A61B5/00 A61B5/01 A61B5/024 A61B5/08 A61B5/145 A61M37/00		
CPC分类号	A61B5/024 A61M2230/65 A61B5/0531 A61B5/14532 A61M15/00 A61M16/0051 A61M16/0066 A61M16/06 A61M16/0683 A61M2016/0036 A61M2205/3553 A61M2205/3561 A61M2205/3584 A61M2205/50 A61M2205/581 A61M2205/583 A61M2230/06 A61M2230/10 A61M2230/201 A61M2230/42 A61M2230/50 A61B5/0476 A61M16/0069 A61M16/024		
优先权	2006900780 2006-02-17 AU		
其他公开文献	US8640698		
外部链接	Espacenet USPTO		

摘要(译)

根据本发明的某些示例性实施例，提供了一种用于治疗患有睡眠呼吸障碍和糖尿病的患者的装置。 PAP装置可以配置成提供加压可呼吸气体的供应。还可以提供至少一种血糖传感器。控制器可操作以从至少一个血糖检测器接收信号，并且可进一步操作以分析信号以指示血糖异常（例如，低血糖，高血糖，糖尿病昏迷等）。可选地，当信号指示患者正在经历糖尿病事件时，可以产生警报和/或药物输送单元可以对患者进行适当的治疗。