DELIVERING VARIABLE POSITIVE AIRWAY PRESSURE DEPENDING ON AWAKE STATE AND SLEEP DISORDERED BREATHING

BACKGROUND

Field

[0001] The present disclosure relates to systems for treating obstructive sleep apnea by providing positive airway pressure to a patient, in particular, to methods for the device to adjust the treatment pressure in response to the patient's awake state and sleep disordered breathing.

Description of Related Art

[0002] One major treatment approach for obstructive sleep apnea includes providing breathing gases to the patient throughout the period the patient is asleep. These treatments may collectively be known as positive airway pressure therapy (PAP). Variations on this therapy include having different inspiration and expiration pressures, commonly known as bi-level or bi-PAP, or having continuously adjusting therapy which responds to breathing events.

SUMMARY

[0003] The systems, methods and devices described herein have innovative aspects, no single one of which is indispensable or solely responsible for their desirable attributes. Without limiting the scope of the claims, some of the advantageous features will now be summarized.

[0004] The present disclosure describes a positive airway pressure system that delivers gas to a patient when asleep, the gas having a pressure within a range of asleep pressures, and a different awake pressure when the patient is awake, the awake pressure being lower than the minimum pressure in the range of asleep pressures. This can advantageously improve the comfort of the device for a patient, which can increase compliance with the positive airway pressure therapy. Increased compliance generally improves the results of the therapy for the patient.

[0005] In a first aspect, a positive airway pressure ~~system~~ device is provided which includes a flow generator configured to provide gas at a pressure to a patient. ~~The positive airway pressure system also includes a user interface configured to provide to the patient the gas at the pressure and a conduit that provides a path for the gas from the flow generator to the user interface.~~ The positive airway pressure system also includes a

sensor configured to measure breathing of the patient. The positive airway pressure system also includes a control system configured to detect sleep disordered breathing based at least in part on analysis of data acquired by the sensor; determine a sleep state of the patient based at least in part on analysis of data acquired by the sensor; control the flow generator to provide a pressure between a low pressure, which is greater than or equal to about 4 cmH_2O, and a high pressure, which is less than or equal to about 20 cmH_2O, when the sleep state is determined to be asleep, the pressure provided based at least in part on whether sleep disordered breathing is detected; and control the flow generator to provide an awake pressure ~~different from~~lower than the low asleep pressure if the sleep state is determined to be awake, wherein the awake pressure is ~~selected~~ selectable by a user and is a therapeutic pressure greater than or equal to about 4 cmH_2O.

[0006] In some embodiments of the first aspect, the awake pressure is a therapeutic pressure. In some embodiments of the first aspect, the awake pressure is lower than the low pressure.

[0007] In some embodiments of the first aspect, the controller is further configured to control the flow generator to provide a pressure which increases over time at a first pressure ramp rate when the pressure being provided by the flow generator is the awake pressure and the sleep state is determined to be asleep or sleep disordered breathing is detected. In a further embodiment, the first pressure ramp rate is adjustable by a user. In some embodiments of the first aspect, the controller is further configured to control the flow generator to provide a pressure which decreases over time at a second pressure ramp rate when the pressure being provided by the flow generator is between the low pressure and the high pressure and the sleep state is determined to be awake. In a further embodiment, the second pressure ramp rate is adjustable by a user.

[0008] In some embodiments of the first aspect, the low pressure and the high pressure are adjustable by a user. In some embodiments of the first aspect, the sensor is one of a flow sensor, a pressure sensor, a sound sensor, a motion sensor, or a plethysmograph sensor.

[0008a] In a second aspect, a positive airway pressure system is provided that comprises the positive airway pressure device of the first aspect and also comprises a user interface configured to provide to the patient the gas at the pressure and a conduit that provides a path for the gas from the flow generator to the user interface.

[0009] In a ~~second~~ third aspect, a method is provided for supplying positive airway pressure therapy to a patient. The method includes receiving input from a user to set an awake pressure, detecting a presence of sleep disordered breathing; determining a sleep state of the patient; if the sleep state is determined to be asleep, delivering gas having an asleep pressure that is adjusted between a low asleep pressure, which is greater than or equal to about 4 cmH_2O, and a high asleep pressure, which is less than or equal to about 20 cmH_2O, the asleep pressure depending at least in part on the presence of sleep disordered breathing; and if the sleep state is determined to be awake, delivering gas having the awake pressure, the awake pressure ~~different from~~is lower than the low asleep pressure, wherein the awake pressure is a therapeutic pressure greater than or equal to about 4 cmH_2O.

[0010] In some embodiments of the ~~second~~ third aspect, the awake pressure is a therapeutic pressure. In some embodiments of the ~~second~~ third aspect, the awake pressure is lower than the low asleep pressure.

[0011] In some embodiments of the ~~second~~ third aspect, the method further includes increasing a pressure of the gas delivered at a first ramp rate when the pressure being delivered has the awake pressure and the sleep state is determined to be asleep or sleep disordered breathing is detected. In a further aspect, the method includes receiving input from a user to set the first ramp rate.

[0012] In some embodiments of the ~~second~~ third aspect, the method includes decreasing a pressure of the gas delivered at a second ramp rate when the pressure being delivered is between the low asleep pressure and the high asleep pressure and the sleep state is determined to be awake. In a further aspect, the method includes receiving input from a user to set the second ramp rate.

[0013] In some embodiments of the ~~second~~ third aspect, the method includes receiving input from a user to set the low asleep pressure and the high asleep pressure. In some embodiments of the ~~second~~ third aspect, detecting a presence of sleep disordered breathing comprises analyzing values from a sensor, the sensor comprising at least one of a flow sensor, a pressure sensor, a sound sensor, a motion sensor, or a plethysmograph.

[0014] In a ~~third~~ fourth aspect, a user interface is provided that is communicably coupled to a control system of a positive airway pressure apparatus. The user interface includes an awake pressure node configured to receive awake pressure data indicative of an awake pressure. The user interface includes a low pressure node configured to receive lower bound data indicative of a lower bound of a pressure range. The user interface includes a high pressure node configured to receive upper bound data indicative of an upper bound of the pressure range. The user interface communicates the awake pressure, the lower bound of the pressure range, and the upper bound of the pressure range to the control system, the lower bound of the pressure range is greater than or equal to about 4 cmH_2O, and the upper bound of the pressure range is less than or equal to about 20 cmH_2O, and the control system controls the positive airway pressure apparatus to supply a breathing gas having the awake pressure if a sleep state is determined to be awake, the awake pressure is ~~different from~~ a therapeutic pressure greater than or equal to about 4 cmH_2O, and the awake pressure is less than the lower bound of the pressure range.

[0015] In some embodiments of the ~~third~~ fourth aspect, the awake pressure is less than the lower bound of the pressure range. In some embodiments of the ~~third~~ fourth aspect, the user interface further includes a ramp rate node configured to receive ramp rate data indicative of a pressure ramp rate. In a further embodiment of the third ~~aspect~~fourth, the

CLAIMS:

1. A positive airway pressure ~~system~~ device, comprising:

a flow generator configured to provide gas at a pressure to a patient;

~~a user interface configured to provide to the patient the gas at the pressure;~~

~~a conduit that provides a path for the gas from the flow generator to the user interface;~~

a sensor configured to measure breathing of the patient; and

a control system configured to:

detect sleep disordered breathing based at least in part on analysis of data acquired by the sensor;

determine a sleep state of the patient based at least in part on analysis of data acquired by the sensor;

control the flow generator to provide a pressure between a low pressure, which is greater than or equal to about 4 cmH_2O, and a high pressure, which is less than or equal to about 20 cmH_2O, when the sleep state is determined to be asleep, the pressure provided based at least in part on whether sleep disordered breathing is detected; and

control the flow generator to provide an awake pressure ~~different from~~lower than the low asleep pressure if the sleep state is determined to be awake, wherein the awake pressure is ~~selected~~ selectable by a user and is a therapeutic pressure greater than or equal to about 4 cmH_2O.

~~2. The positive airway pressure system of Claim 1, wherein the awake pressure is a therapeutic pressure.~~

~~3.~~2. The positive airway pressure ~~system~~ device of Claim 1 ~~or Claim 2~~, wherein the ~~controller~~ control system is further configured to control the flow generator to provide a pressure which increases over time at a first pressure ramp rate when the pressure being provided by the flow generator is the awake pressure and the sleep state is determined to be asleep or sleep disordered breathing is detected.

~~4.~~3. The positive airway pressure ~~system~~ device of Claim ~~3~~2, wherein the first pressure ramp rate is adjustable by a user.

~~5.~~4. The positive airway pressure ~~system~~ device of any one of Claims 1 to ~~4~~3, wherein the ~~controller~~ control system is further configured to control the flow generator to provide a pressure which decreases over time at a second pressure ramp rate when the pressure being provided by the flow generator is between the low pressure and the high pressure and the sleep state is determined to be awake.

~~6.~~5. The positive airway pressure ~~system~~ device of Claim ~~5~~4, wherein the second pressure ramp rate is adjustable by a user.

~~7.~~6. The positive airway pressure ~~system~~ device of any one of Claims 1 to ~~6~~5, wherein the low pressure and the high pressure are adjustable by a user.

~~8.~~7. The positive airway pressure ~~system~~ device of any one of Claims ~~3~~ 2 to ~~7~~6, wherein the sensor is ~~one of~~chosen among a flow sensor, a pressure sensor, a sound sensor, a motion sensor, or a plethysmograph.

8. The positive airway pressure device of any one of Claims 1 to 7, wherein the low pressure and the high pressure when the sleep state is determined to be asleep bracket a determined, targeted, or optimal pressure.

9. The positive airway pressure device of any one of Claims 2 to 8, wherein the control system is configured to detect sleep disordered breathing upon the occurrence of an exit trigger.

10. The positive airway pressure device of claim 9, wherein the exit trigger is two apnea events within a moving window of 30 consecutive breaths, or two hypopnea events within a moving window of 30 consecutive breaths.

11. The positive airway pressure device of claim 1, wherein the control system is configured to:

control the flow generator to provide a pressure between 4 and 20 cmH_2O when the sleep state is determined to be asleep, wherein P_{min} is greater than 4 cmH_2O, P_{max} is less than or equal to 20 cmH_2O, P_{min} is less than P_{max} and the pressure provided is based at least in part on whether sleep disordered breathing is detected; and

control the flow generator to provide an awake pressure P_{awake} lower than P_{min} if the sleep state is determined to be awake, wherein the awake pressure P_{awake} is selectable by a user and is a therapeutic pressure greater than or equal to 4 cmH_2O.

12. A positive airway pressure system comprising:

the positive airway pressure device of any one of the preceding claims;

a user interface configured to provide to the patient the gas at the pressure; and

a conduit that provides a path for the gas from the flow generator to the user interface.

~~9.~~13. A method of providing positive airway pressure therapy to a patient, the method comprising:

receiving input from a user to set an awake pressure;

detecting a presence of sleep disordered breathing;

determining a sleep state of the patient;

if the sleep state is determined to be asleep, delivering gas having an asleep pressure that is adjusted between a low asleep pressure, which is greater than or equal to about 4 cmH_2O, and a high asleep pressure, which is less than or equal to about 20 cmH_2O, the asleep pressure depending at least in part on the presence of sleep disordered breathing; and

if the sleep state is determined to be awake, delivering gas having the awake pressure, the awake pressure is lower than the low asleep pressure, wherein the awake pressure is a therapeutic pressure greater than or equal to about 4 cmH_2O.

~~10. The method of Claim 9, wherein the awake pressure is a therapeutic pressure.~~

~~11.~~14. The method of Claim ~~9 or Claim 10~~13, further comprising increasing a pressure of the gas delivered at a first ramp rate when the pressure being delivered has the awake pressure and the sleep state is determined to be asleep or sleep disordered breathing is detected.

~~12.~~15. The method of Claim ~~11~~14, further comprising receiving input from a user to set the first ramp rate.

~~13.~~16. The method of any one of Claims ~~9 to 12~~14 to 15, further comprising decreasing a pressure of the gas delivered at a second ramp rate when the pressure being delivered is

between the low asleep pressure and the high asleep pressure and the sleep state is determined to be awake.

~~14.~~17. The method of Claim ~~13~~16, further comprising receiving input from a user to set the second ramp rate.

~~15.~~18. The method of any one of Claims ~~9~~ 13 to ~~14~~17, further comprising receiving input from a user to set the low asleep pressure and the high asleep pressure.

~~16.~~19. The method of any one of Claims ~~9~~ 13 to ~~15~~18, wherein detecting a presence of sleep disordered breathing comprises analyzing values from a sensor, the sensor comprising at least one of a flow sensor, a pressure sensor, a sound sensor, a motion sensor, or a plethysmograph.

~~17.~~20. A user interface communicably coupled to a control system of a positive airway pressure apparatus, the user interface comprising:

an awake pressure node configured to receive awake pressure data indicative of an awake pressure;

a low pressure node configured to receive lower bound data indicative of a lower bound of a pressure range; and

a high pressure node configured to receive upper bound data indicative of an upper bound of the pressure range,

wherein the user interface communicates the awake pressure, the lower bound of the pressure range, and the upper bound of the pressure range to the control system, ~~and~~

wherein the lower bound of the pressure range is greater than or equal to about 4 cmH_2O, and the upper bound of the pressure range is less than or equal to about 20 cmH_2O, and

wherein the control system controls the positive airway pressure apparatus to supply a breathing gas having the awake pressure if a sleep state is determined to be awake, the awake pressure is a therapeutic pressure greater than or equal to about 4 cmH_2O, and the awake pressure is less than the lower bound of the pressure range.

~~18.~~21. The user interface of Claim ~~17~~20, further comprising a ramp rate node configured to receive ramp rate data indicative of a pressure ramp rate.

~~19.~~22. The user interface of Claim ~~18~~21, wherein the control system transitions from providing the awake pressure to a pressure within the pressure range at the pressure ramp rate.