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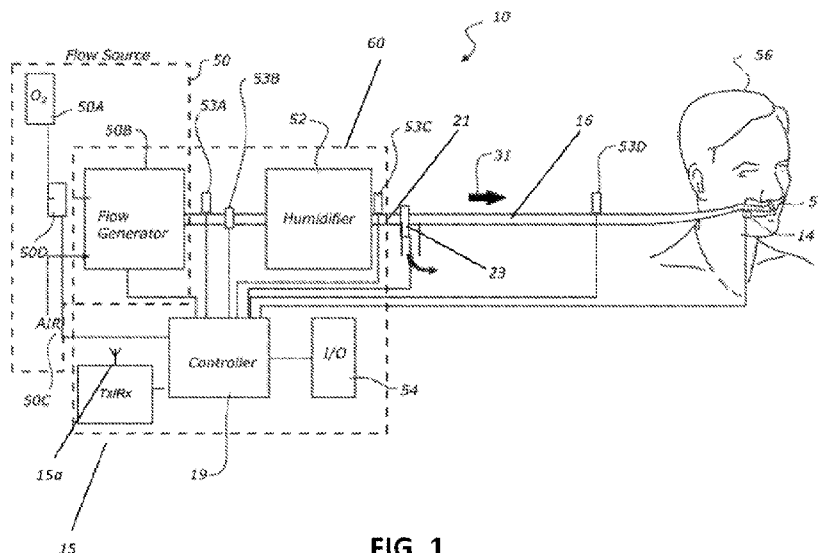


FIG. 1

(57) **Abstract:** A method of estimating an off-therapy respiratory parameter of a patient during therapy is provided. The method includes the steps of providing a flow of gases at a plurality of flow rates via a flow generator, the flow rates comprising at least an operating flow rate and one or more intermediate flow rates; receiving flow parameter data indicative or representative of one or more properties the flow of gases provided by the flow generator at each of the plurality of flow rates from one or more sensors; estimating or determining a respiratory parameter of the patient at each of the plurality of flow rates based at least on the data received; and estimating an off-therapy respiratory parameter of the patient based at least on the estimated or determined respiratory parameters at each of the plurality of flow rates.

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ESTIMATING RESPIRATORY PARAMETERS IN RESPIRATORY SYSTEMS

FIELD OF THE DISCLOSURE

The present disclosure relates to a respiratory apparatus for providing a flow of gases, a method for controlling a respiratory apparatus for providing a flow of gases to a user, and a respiratory system for providing a flow of gases to a user. More specifically, this disclosure relates to estimating off-therapy respiratory parameters during use of a respiratory system by a patient.

BACKGROUND

Respiratory apparatuses are used in various environments such as hospital, medical facility, residential care, or home environments to deliver a flow of gases to users or patients. A breathing assistance or respiratory therapy apparatus (collectively, “respiratory apparatus” or “respiratory devices”) may be used to deliver supplementary oxygen or other gases with a flow of gases, and/or a humidification apparatus to deliver heated and humidified gases. A respiratory apparatus may allow adjustment and control over characteristics of the gases flow, including flow rate, temperature, gases concentration, humidity, pressure, etc. Sensors, such as flow sensors and/or pressure sensors are used to measure characteristics of the gases flow.

SUMMARY

In a **first** aspect, the present disclosure broadly comprises a method of estimating an off-therapy respiratory parameter of a patient during therapy, the method comprising: providing a flow of gases at a plurality of flow rates via a flow generator, the flow rates comprising at least an operating flow rate and one or more intermediate flow rates; receiving flow parameter data indicative or representative of one or more properties of the flow of gases provided by the flow generator at each of the plurality of flow rates from one or more sensors; estimating or determining a respiratory parameter of the patient at each of the plurality of flow rates, based at least in part on the flow parameter data received; and estimating an off-therapy respiratory parameter of the patient based at least in part on the estimated or determined respiratory parameters at each of the plurality of flow rates.

In a configuration, the flow parameter data comprises flow rate data indicative or representative of the flow rate of the flow of gases provided by the flow generator.

In a configuration, the flow parameter data comprises pressure data indicative or representative of the pressure of the flow of gases provided by the flow generator.

In a configuration, the step of estimating or determining the respiratory parameter of the patient at each of the plurality of flow rates comprises assessing the flow parameter data.

In a configuration, the respiratory parameter of the patient is the respiratory rate of the patient. In a configuration, the respiratory parameter of the patient is the inspiratory-expiratory time ratio of the patient.

In a configuration, the step of estimating or determining the respiratory rate of the patient at each of the plurality of flow rates, comprises: performing a frequency analysis of the flow parameter data at an intermediate flow rate; identifying a plurality of local maxima of a signal resulting from the frequency analysis; and outputting a frequency corresponding to a frequency component with the highest magnitude among the plurality of local maxima as an estimated respiratory rate of the patient.

In a configuration, the operating flow rate comprises a therapeutic flow rate. In a configuration, the one or more intermediate flow rates comprise one or more sub-therapeutic flow rates, and wherein the one or more sub-therapeutic flow rates are lower than the operating flow rate.

In a configuration, the step of providing the flow of gases at a plurality of flow rates comprises at one or more time intervals adjusting the flow rate to a different intermediate flow rate.

In a configuration, the step of estimating or determining a respiratory parameter of the patient occurs at each time interval.

In a configuration, the intermediate flow rate is reduced at each time interval.

In a configuration, an intermediate flow rate may comprise a minimum flow rate.

In a configuration, adjusting the flow rate to a different intermediate flow rate comprises ramping the flow rate gradually from the present flow rate to the different intermediate flow rate.

In a configuration, the flow rate is maintained for a minimum or predetermined period of time at each of the one or more intermediate flow rates, before the step of estimating or determining a respiratory parameter of the patient at each flow rate occurs.

In a configuration, the minimum or predetermined period of time is inversely proportional to an estimated respiratory parameter of the patient. The minimum or predetermined period of time is at least long enough to enable residual effects of the previous flow rate on the respiratory parameter of the patient to decay.

In a configuration, the method further comprises returning to the operating flow rate after the step of estimating an off-therapy respiratory parameter of the patient. The returning to the operating flow rate comprises first increasing the operating flow rate to one or more intermediate flow rates. The operating flow rate may be increased to one or more intermediate flow rates at gradual intervals before returning to the operating flow rate.

In a configuration, the method further comprises the steps of: receiving flow parameter data at the operating flow rate; and estimating or determining a respiratory parameter of the patient at the operating flow rate based at least on the flow parameter data.

In a configuration, the step of estimating an off-therapy respiratory parameter of the patient is based at least on the estimated or determined respiratory parameters at each of the one or more intermediate flow rates and at the operating flow rate.

In a configuration, the flow parameter data comprises oxygen concentration data indicative or representative of the concentration of oxygen of the flow of gases provided by the flow generator.

In a configuration, estimating an off-therapy respiratory parameter of the patient is further based on at least the flow rate data received at each of the plurality of flow rates.

In a configuration, estimating an off-therapy respiratory parameter of the patient is further based on the oxygen concentration data received at each of the plurality of intermediate flow rates.

In a configuration, the step of estimating the off-therapy respiratory parameter of the patient is performed by a model, wherein the model takes as input at least the estimated or determined respiratory parameters at each of the plurality of flow rates. In a configuration, the model further takes as input the flow parameter data. In a configuration, the model further takes as input the flow parameter data received at the operating flow rate and the flow data received at the one or more intermediate flow rates.

In a configuration, the model is a linear model and comprises coefficients that define a relationship between the inputted estimated or determined respiratory parameters and the flow parameter data at each flow rate. In a configuration, the model further comprises parameters that relate the estimated or determined respiratory parameter and the flow parameter data at each flow rate. The parameters of the model may comprise at least one or more of:

- an average of the estimated or determined respiratory parameter of the patient at each of the plurality of flow rates;
- a difference between the operating flow rate and a/the minimum flow rate;
- a difference between the respiratory parameter of the patient at the operating flow rate and an average of the estimated or determined respiratory parameter of the patient at each of the one or more intermediate flow rates, wherein the difference is divided by a difference between the operating flow rate and the one or more intermediate flow rates;

- a difference between the oxygen concentration data of the flow of gases at one or more intermediate flow rates and an ambient reading of oxygen concentration level.

In a configuration, the model is configured to output a value corresponding to an estimation of the respiratory parameter of the patient if the flow generator was providing no flow. In a configuration, the model is configured to output a value relating an expected change in the respiratory parameter of the patient based on a change in flow rate.

In a configuration, the value outputted relates an expected change in the respiratory parameter of the patient to an increase in flow rate from zero to a pre-determined operating flow rate for therapeutic flow rate.

In a configuration, the model comprises a fitted linear equation, wherein the fitted linear equation takes as input the estimates of a respiratory parameter of the patient at each flow rate, and measurements of said flow rates. In a configuration, the fitted linear equation takes the form of a series of linear terms. The fitted linear equation may extrapolate the respiratory parameter of the patient based on an input of the estimated or determined respiratory parameter at each of the plurality of intermediate flow rates.

In a configuration, the fitted linear equation is configured to output an extrapolated respiratory parameter of the patient based on an input of at least the estimated or determined respiratory parameter determined at each of the plurality of flow rates. The extrapolated respiratory parameter of the patient is an approximation of the respiratory parameter of the patient at a flow rate below at least the lowest intermediate flow rate.

In a configuration, the off-therapy respiratory parameter of the patient is estimated while the respiratory therapy system is supplying air to the airway of the patient. The off-therapy respiratory parameter of the patient may be estimated while the respiratory therapy system is providing a flow of gases to the airways of the patient.

In a configuration, the method further comprises determining a difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient.

In a configuration, the determination of the difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient is further based on one or more average values of off-therapy respiratory parameter of the patient determined over multiple therapy sessions and/or multiple flow rate reduction and respiratory parameter estimation cycles over one therapy session.

In a configuration, wherein the method further comprises determining a status of the patient's respiratory parameter based on the flow parameter data.

In a configuration, the method further comprises controlling the flow generator to provide the flow of gases at the plurality of intermediate flow rates based on the status of the patient's respiratory parameter indicating that the patient's respiratory parameter is substantially stable.

In a configuration, the step of determining the status of the patient's respiratory parameter comprises: determining an indication or estimate of the respiratory parameter of the patient based on flow parameter data received at a plurality of intervals while at the operating flow rate, and comparing the indication or estimate of the respiratory parameter of the patient at each interval to at least the indication or estimate of the respiratory parameter of the patient at one or more previous intervals.

In a configuration, wherein the status of the patient's respiratory parameter relates to a degree or amount of change between the indication or estimate of the respiratory parameter of the patient determined at a present interval to the indication or estimate of the respiratory parameter of the patient determined at one or more previous intervals, based on said comparison.

In a configuration, the method further comprises sending or transmitting data representing the estimated off-therapy respiratory parameter of the patient to an external device via a data communication protocol.

In a configuration, the method further comprises adjusting one or more parameters of or associated with the flow generator based at least partly on the estimated off-therapy respiratory parameter of the patient.

In a configuration, the method further comprises generating or providing suggested thresholds and/or parameters associated with the one or more thresholds based at least partly on the estimated off-therapy respiratory parameter of the patient.

In a configuration, the method further comprises generating an alert, alarm, and/or notification comprising data indicative of suggested adjustments to one or more therapy settings based at least partly on the estimated off-therapy respiratory parameter of the patient, and one or more thresholds. The therapy settings may comprise a flow rate setting and/or an FiO_2 setting.

In a configuration, the method is configured for use in a non-sealed respiratory therapy system. The method is configured for use in the delivery of a nasal high flow therapy.

In a configuration, the value outputted relates an expected change in the respiratory parameter of the patient to an increase in flow rate from zero to a pre-determined operating flow rate for therapeutic flow rate.

In a configuration, the fitted linear equation takes the form of a series of linear terms.

In a **second** aspect, the present disclosure broadly comprises a respiratory apparatus configured to provide a flow of gases to a patient, comprising: a flow generator configured to generate the flow of gases for the patient at a plurality of flow rates; one or more sensors each configured to generate flow parameter data indicative or representative of one or more properties of the flow of gases; and a controller, wherein the controller is configured to:

control the flow generator to provide a flow of gases at the plurality of flow rates, the plurality of flow rates comprising least at an operating flow rate and one or more intermediate flow rates; receive flow parameter data from the one or more sensors at each of the plurality of flow rates; estimate or determine a respiratory parameter of the patient at each of the plurality of flow rates based at least in part on the flow parameter data received; and estimate an off-therapy respiratory parameter of the patient based at least in part on the estimated or determined respiratory parameter determined at each of the plurality of flow rates.

In a configuration, the flow parameter data comprises flow rate data indicative or representative of the flow rate of the flow of gases provided by the flow generator.

In a configuration, the flow parameter data comprises pressure data indicative or representative of the pressure of the flow of gases at an outlet of the blower of the flow generator.

In a configuration, the controller is configured to estimate or determine the respiratory parameter of the patient at each of the plurality of flow rates by assessing the flow parameter data.

In a configuration, the respiratory parameter of the patient is a respiratory rate of the patient. In another configuration, the respiratory parameter of the patient is an inspiratory-expiratory time ratio of the patient.

In a configuration, the controller is configured to estimate or determine the respiratory rate of the patient at each of the plurality of flow rates, by: performing a frequency analysis of the flow parameter data at an intermediate flow rate; identifying a plurality of local maxima of a signal resulting from the frequency analysis; and outputting a frequency corresponding to a frequency component with the highest magnitude among the plurality of local maxima as an estimated respiratory rate of the patient.

In a configuration, the operating flow rate comprises a therapeutic flow rate. In a configuration, the one or more intermediate flow rates comprise one or more sub-therapeutic flow rates, and wherein the one or more sub-therapeutic flow rates are lower than the operating flow rate.

In a configuration, the controller is configured to control the flow generator to provide the flow of gases at a plurality of flow rates by, at one or more time intervals, adjusting the flow rate to a different intermediate flow rate.

In a configuration, the controller is configured to estimate or determine a respiratory parameter of the patient at each time interval.

In a configuration, the intermediate flow rate at each time interval is reduced at each time interval. In a configuration, an intermediate flow rate may comprise a minimum flow rate. In a configuration, adjusting the flow rate to a different intermediate flow rate comprises ramping the flow rate gradually from the present flow rate to the different intermediate flow rate.

In a configuration, the controller is configured to maintain the flow rate for a minimum or predetermined period of time at each of the one or more intermediate flow rates, before estimating or determining a respiratory parameter of the patient at each flow rate.

In a configuration, the predetermined period of time is inversely proportional to an estimated respiratory parameter of the patient.

In a configuration, the predetermined period of time is at least long enough to enable residual effects of the previous flow rate on the respiratory parameter of the patient to decay.

In a configuration, the controller is further configured to control the flow generator to return to the operating flow rate after estimating an off-therapy respiratory parameter of the patient.

In a configuration, the returning to the operating flow rate comprises first increasing the operating flow rate to one or more intermediate flow rates. The operating flow rate may be increased to one or more intermediate flow rates at gradual intervals before returning to the operating flow rate.

In a configuration, the controller is further configured to: receive flow parameter data at the operating flow rate; and estimate or determine a respiratory parameter of the patient at the operating flow rate based at least on said flow parameter data.

In a configuration, wherein the controller is configured to estimate an off-therapy respiratory parameter of the patient based at least on the estimated or determined respiratory parameters at each of the one or more intermediate flow rates and at the operating flow rate.

In a configuration, the flow parameter data comprises oxygen concentration data indicative or representative of the concentration of oxygen of the flow of gases provided by the flow generator.

In a configuration, the controller is configured to estimate an off-therapy respiratory parameter of the patient based on at least the flow rate data received at each of the plurality of flow rates.

In a configuration, the controller is configured to estimate an off-therapy respiratory parameter of the patient based further on the oxygen concentration data received at each of the plurality of intermediate flow rates.

In a configuration, the controller is configured to estimate the off-therapy respiratory parameter of the patient using a model, wherein the model takes as input at least the estimated or determined respiratory parameters at each of the plurality of flow rates. In a configuration, the model takes as input the flow parameter data.

In a configuration, the model takes as input the flow parameter data received at the operating flow rate and the flow data received at the one or more intermediate flow rates.

In a configuration, the model is a linear model and comprises coefficients that define a relationship between the inputted estimated or determined respiratory parameters and the flow parameter data at each flow rate. In a configuration, the model further comprises parameters that relate the estimated or determined respiratory parameter and the flow parameter data at each flow rate. The parameters of the model may comprise at least one or more of:

- an average of the estimated or determined respiratory parameter of the patient at each of the plurality of flow rates;
- a difference between the operating flow rate and a/the minimum flow rate;
- a difference between the respiratory parameter of the patient at the operating flow rate and an average of the estimated or determined respiratory parameter of the patient at each of the one or more intermediate flow rates, wherein the difference is divided by a difference between the operating flow rate and the one or more intermediate flow rates;
- a difference between the oxygen concentration data of the flow of gases at one or more intermediate flow rates and an ambient reading of oxygen concentration level.

In a configuration, the model is configured to output a value corresponding to an estimation of the respiratory parameter of the patient if the respiratory therapy apparatus was providing no flow.

In a configuration, the model is configured to output a value relating an expected change in the respiratory parameter of the patient based on a change in flow rate.

In a configuration, the value outputted relates an expected change in the respiratory parameter of the patient to an increase in flow rate from zero to a pre-determined operating flow rate for therapeutic flow rate.

In a configuration, the model comprises a fitted linear equation, wherein the fitted linear equation takes as input the estimates of a respiratory parameter of the patient at each flow rate, and measurements of said flow rates.

In a configuration, the fitted linear equation takes the form of a series of linear terms.

In a configuration, the fitted linear equation extrapolates the respiratory parameter of the patient based at least on an input of the estimated or determined respiratory parameter at each of the plurality of intermediate flow rates.

In a configuration, the fitted linear equation is configured to output an extrapolated respiratory parameter of the patient based on an input of at least the estimated or determined respiratory parameter determined at each of the plurality of flow rates.

In a configuration, the extrapolated respiratory parameter of the patient is an approximation of the respiratory parameter of the patient at a flow rate below at least the lowest intermediate flow rate.

In a configuration, the off-therapy respiratory parameter of the patient is estimated while the respiratory apparatus is providing a flow of gases to the airway of the patient.

In a configuration, the off-therapy respiratory parameter of the patient is estimated while the patient is using the respiratory apparatus for therapeutic purposes.

In a configuration, the controller is further configured to determine a difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient.

In a configuration, the determination of the difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient is further based on one or more average values of off-therapy respiratory parameter of the patient determined over multiple therapy sessions and/or multiple flow rate reduction and respiratory parameter estimation cycles over one therapy session.

In a configuration, the controller is further configured to determine a status of the patient's respiratory parameter based on the flow parameter data.

In a configuration, the controller is further configured to control the flow generator to provide the flow of gases at the plurality of intermediate flow rates based on the status of the patient's respiratory parameter indicating that the patient's respiratory parameter is substantially stable.

In a configuration, the controller is configured to determine the status of the patient's respiratory parameter by: determining an indication or estimate of the respiratory parameter of the patient based on flow parameter data received at a plurality of intervals while at the operating flow rate, and comparing the indication or estimate of the respiratory parameter of the patient at each interval to at least the indication or estimate of the respiratory parameter of the patient at one or more previous intervals.

In a configuration, the status of the patient's respiratory parameter relates to a degree of change between the indication or estimate of the respiratory parameter of the patient determined at a present interval to the indication or estimate of the respiratory parameter of the patient determined at one or more previous intervals, based on said comparison.

In a configuration, the controller is further configured to transmit data representing the estimated off-therapy respiratory parameter of the patient to a device or system that is in data communication with the apparatus.

In a configuration, the controller is further configured to adjust one or more parameters of the respiratory apparatus based at least partly on the estimated off-therapy respiratory parameter of the patient.

In a configuration, the controller is further configured to generate suggested thresholds and/or parameters associated with the one or more thresholds based at least partly on the estimated off-therapy respiratory parameter of the patient.

In a configuration, the controller is further configured to generate an alert, alarm, and/or notification comprising data indicative of suggested adjustments to one or more therapy settings based at least partly on the estimated off-therapy respiratory parameter of the patient, and one or more thresholds. The therapy settings may comprise a flow rate setting and/or an FiO_2 setting.

In a configuration, the respiratory apparatus is configured for use in a non-sealed respiratory therapy system. The respiratory apparatus may be configured for use in the delivery of a nasal high flow therapy.

In a configuration, the value outputted relates an expected change in the respiratory parameter of the patient to an increase in flow rate from zero to a pre-determined operating flow rate for therapeutic flow rate.

In a configuration, the fitted linear equation takes the form of a series of linear terms.

In a **third** aspect, the present disclosure broadly comprises a respiratory therapy system configured to provide a flow of gases to a user, comprising: a flow generator configured to generate the flow of gases for the user at a plurality of flow rates; one or more sensors each configured to generate flow parameter data indicative or representative of one or more properties of the flow of gases; a breathing conduit operatively coupled to the flow generator and configured to convey the flow of gases from the flow generator to the user; a patient interface operatively coupled to the breathing conduit; and a controller, wherein the controller is configured to: control the flow generator to provide a flow of gases at the plurality of flow rates, the plurality of flow rates comprising least at an operating flow rate and one or more intermediate flow rates; receive flow parameter data from the one or more sensors at each of the plurality of flow rates; estimate or determine a respiratory parameter of the patient at each of the plurality of flow rates based at least on the flow parameter data; and estimate an off-therapy respiratory parameter of the patient based at least on the estimated or determined respiratory parameter determined at each of the plurality of flow rates.

In a configuration, the flow parameter data comprises flow rate data indicative or representative of the flow rate of the flow of gases provided by the flow generator.

In a configuration, the flow parameter data comprises pressure data indicative or representative of the pressure of the flow of gases at an outlet of the blower of the flow generator.

In a configuration, the controller is configured to estimate or determine the respiratory parameter of the patient at each of the plurality of flow rates by assessing the flow parameter data.

In a configuration, the respiratory parameter of the patient is a respiratory rate of the patient. In another configuration, the respiratory parameter of the patient is an inspiratory-expiratory time ratio of the patient.

In a configuration, the controller is configured to estimate or determine the respiratory rate of the patient at each of the plurality of flow rates, by: performing a frequency analysis of the flow parameter data at an intermediate flow rate; identifying a plurality of local maxima of a signal resulting from the frequency analysis; and outputting a frequency corresponding to a frequency component with the highest magnitude among the plurality of local maxima as an estimated respiratory rate of the patient.

In a configuration, the operating flow rate comprises a therapeutic flow rate. In a configuration, the one or more intermediate flow rates comprise one or more sub-therapeutic flow rates, and wherein the one or more sub-therapeutic flow rates are lower than the operating flow rate.

In a configuration, the controller is configured to control the flow generator to provide the flow of gases at a plurality of flow rates by, at one or more time intervals, adjusting the flow rate to a different intermediate flow rate.

In a configuration, the controller is configured to estimate or determine a respiratory parameter of the patient at each time interval.

In a configuration, the intermediate flow rate at each time interval is reduced at each time interval. In a configuration, an intermediate flow rate may comprise a minimum flow rate. In a configuration, adjusting the flow rate to a different intermediate flow rate comprises ramping the flow rate gradually from the present flow rate to the different intermediate flow rate.

In a configuration, the controller is configured to maintain the flow rate for a predetermined period of time at each of the one or more intermediate flow rates, before estimating or determining a respiratory parameter of the patient at each flow rate.

In a configuration, the predetermined period of time is inversely proportional to an estimated respiratory parameter of the patient.

In a configuration, the predetermined period of time is at least long enough to enable residual effects of the previous flow rate on the respiratory parameter of the patient to decay.

In a configuration, the controller is further configured to control the flow generator to return to the operating flow rate after estimating an off-therapy respiratory parameter of the patient.

In a configuration, the returning to the operating flow rate comprises first increasing the operating flow rate to one or more intermediate flow rates. The operating flow rate may be increased to one or more intermediate flow rates at gradual intervals before returning to the operating flow rate.

In a configuration, the controller is further configured to: receive flow parameter data at the operating flow rate; and estimate or determine a respiratory parameter of the patient at the operating flow rate based at least on said flow parameter data.

In a configuration, wherein the controller is configured to estimate an off-therapy respiratory parameter of the patient based at least on the estimated or determined respiratory parameters at each of the one or more intermediate flow rates and at the operating flow rate.

In a configuration, the flow parameter data comprises oxygen concentration data indicative or representative of the concentration of oxygen of the flow of gases provided by the flow generator.

In a configuration, the controller is configured to estimate an off-therapy respiratory parameter of the patient based on at least the flow rate data received at each of the plurality of flow rates.

In a configuration, the controller is configured to estimate an off-therapy respiratory parameter of the patient based further on the oxygen concentration data received at each of the plurality of intermediate flow rates.

In a configuration, the controller is configured to estimate the off-therapy respiratory parameter of the patient using a model, wherein the model takes as input at least the estimated or determined respiratory parameters at each of the plurality of flow rates. In a configuration, the model takes as input the flow parameter data.

In a configuration, the model takes as input the flow parameter data received at the operating flow rate and the flow data received at the one or more intermediate flow rates.

In a configuration, the model is a linear model and comprises coefficients that define a relationship between the inputted estimated or determined respiratory parameters and the flow parameter data at each flow rate. In a configuration, the model further comprises parameters that relate the estimated or determined respiratory parameter and the flow parameter data at each flow rate. The parameters of the model may comprise at least one or more of:

- an average of the estimated or determined respiratory parameter of the patient at each of the plurality of flow rates;

- a difference between the operating flow rate and a/the minimum flow rate;
- a difference between the respiratory parameter of the patient at the operating flow rate and an average of the estimated or determined respiratory parameter of the patient at each of the one or more intermediate flow rates, wherein the difference is divided by a difference between the operating flow rate and the one or more intermediate flow rates;
- a difference between the oxygen concentration data of the flow of gases at one or more intermediate flow rates and an ambient reading of oxygen concentration level.

In a configuration, the model is configured to output a value corresponding to an estimation of the respiratory parameter of the patient if the respiratory therapy apparatus was providing no flow.

In a configuration, the model is configured to output a value relating an expected change in the respiratory parameter of the patient based on a change in flow rate.

In a configuration, the value outputted relates an expected change in the respiratory parameter of the patient to an increase in flow rate from zero to a pre-determined operating flow rate for therapeutic flow rate.

In a configuration, the model comprises a fitted linear equation, wherein the fitted linear equation takes as input the estimates of a respiratory parameter of the patient at each flow rate, and measurements of said flow rates.

In a configuration, the fitted linear equation takes the form of a series of linear terms.

In a configuration, the fitted linear equation extrapolates the respiratory parameter of the patient based at least on an input of the estimated or determined respiratory parameter at each of the plurality of intermediate flow rates.

In a configuration, the fitted linear equation is configured to output an extrapolated respiratory parameter of the patient based on an input of at least the estimated or determined respiratory parameter determined at each of the plurality of flow rates.

In a configuration, the extrapolated respiratory parameter of the patient is an approximation of the respiratory parameter of the patient at a flow rate below at least the lowest intermediate flow rate.

In a configuration, the off-therapy respiratory parameter of the patient is estimated while the respiratory apparatus is providing a flow of gases to the airway of the patient.

In a configuration, the off-therapy respiratory parameter of the patient is estimated while the patient is using the respiratory apparatus for therapeutic purposes.

In a configuration, the controller is further configured to determine a difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient.

In a configuration, the determination of the difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient is further based on one or more average values of off-therapy respiratory parameter of the patient determined over multiple therapy sessions and/or multiple flow rate reduction and respiratory parameter estimation cycles over one therapy session.

In a configuration, the controller is further configured to determine a status of the patient's respiratory parameter based on the flow parameter data.

In a configuration, the controller is further configured to control the flow generator to provide the flow of gases at the plurality of intermediate flow rates based on the status of the patient's respiratory parameter indicating that the patient's respiratory parameter is substantially stable.

In a configuration, the controller is configured to determine the status of the patient's respiratory parameter by: determining an indication or estimate of the respiratory parameter

of the patient based on flow parameter data received at a plurality of intervals while at the operating flow rate, and comparing the indication or estimate of the respiratory parameter of the patient at each interval to at least the indication or estimate of the respiratory parameter of the patient at one or more previous intervals.

In a configuration, the status of the patient's respiratory parameter relates to a degree of change between the indication or estimate of the respiratory parameter of the patient determined at a present interval to the indication or estimate of the respiratory parameter of the patient determined at one or more previous intervals, based on said comparison.

In a configuration, the controller is further configured to transmit data representing the estimated off-therapy respiratory parameter of the patient to a device or system that is in data communication with the apparatus.

In a configuration, the controller is further configured to adjust one or more parameters of the respiratory apparatus based at least partly on the estimated off-therapy respiratory parameter of the patient.

In a configuration, the controller is further configured to generate suggested thresholds and/or parameters associated with the one or more thresholds based at least partly on the estimated off-therapy respiratory parameter of the patient.

In a configuration, the controller is further configured to generate an alert, alarm, and/or notification comprising data indicative of suggested adjustments to one or more therapy settings based at least partly on the estimated off-therapy respiratory parameter of the patient, and one or more thresholds. The therapy settings may comprise a flow rate setting and/or an FiO₂ setting.

In a configuration, the patient interface is a non-sealed patient interface. The respiratory therapy system may be a non-sealed respiratory therapy system. The respiratory therapy system may be configured for use in the delivery of a nasal high flow therapy.

In a configuration, the value outputted relates an expected change in the respiratory parameter of the patient to an increase in flow rate from zero to a pre-determined operating flow rate for therapeutic flow rate.

In a configuration, the fitted linear equation takes the form of a series of linear terms.

In a **fourth** aspect, the present disclosure broadly comprises a method of estimating an off-therapy respiratory parameter of a patient using a respiratory apparatus configured to provide a flow of gases to a user, the apparatus comprising: a flow generator configured to generate the flow of gases for the user at least at an operating flow rate; one or more sensors each configured to generate flow parameter data indicative or representative of one or more properties of the flow of gases; and a controller, wherein the method is executed or implemented by the controller and comprises the steps of: controlling the flow generator to provide a flow of gases at a plurality of intermediate flow rates; receiving flow parameter data at each of the plurality of intermediate flow rates; estimating or determining a respiratory parameter of the patient at each of the plurality of intermediate flow rates based at least in part on the flow parameter data; and estimating an off-therapy respiratory parameter of the patient based at least in part on the estimated or determined respiratory parameters at each of the plurality of intermediate flow rates.

In a **fifth** aspect, the present disclosure broadly comprises a respiratory therapy system, comprising: a respiratory therapy apparatus, comprising a flow generator configured to provide a flow of gases at least at an operating flow rate, one or more sensors each configured to generate data indicative or representative of one or more properties of the flow of gases, and a controller; and a remote computing device, in communication with the controller of the respiratory therapy apparatus, wherein the remote computing device is configured to: determine or receive an indication of an off therapy respiratory parameter of the patient, wherein the indication of an off therapy respiratory parameter of the patient is based at least in part on said data indicative or representative of one or more properties of the flow of gases.

In a **sixth** aspect, the present disclosure broadly comprises a respiratory therapy apparatus configured to provide a flow of gases to a user, comprising: a flow generator configured to provide a flow of gases at least at an operating flow rate; one or more sensors each configured to generate data indicative or representative of one or more properties of the flow of gases; and a controller, wherein the controller is configured to: adjust the operating flow rate to a plurality of intermediate flow rates; measure or estimate a respiratory parameter of the patient based at least in part on said data indicative or representative of one or more properties of the flow of gases at each flow rate; and determine or estimate an off therapy respiratory parameter based at least in part on the plurality of measured or estimated respiratory parameters of the patient.

In a **seventh** aspect, the present disclosure broadly comprises a respiratory therapy apparatus configured to provide a flow of gases to a user, comprising: a flow generator configured to provide a flow of gases at least at an operating flow rate; one or more sensors each configured to generate data indicative or representative of one or more properties of the flow of gases; and a controller, wherein the controller is configured to: determine or receive an indication of an off therapy respiratory parameter of the patient, the indication of the off therapy respiratory parameter determined based at least in part on the data indicative or representative of one or more properties of the flow of gases, and adjust the operating flow rate based on the indication of an off therapy respiratory parameter.

In an **eighth** aspect, the present disclosure broadly comprises a method of estimating an off-therapy respiratory parameter of a patient during therapy, the method comprising: providing a flow of gases at an operating flow rate via a flow generator; receiving data indicative or representative of one or more properties of the flow of gases provided by the flow generator; estimating or determining a respiratory parameter of the patient at the operating flow rate based at least on the data received; at one or more intervals: adjusting the operating flow rate to an intermediate flow rate, and estimating or determining a respiratory parameter of the based at least on the data received; and estimating the off-therapy respiratory parameter of the patient using a model based at least on the respiratory parameter estimated or determined at each interval and the respiratory parameter estimated or determined at the operating flow rate.

In a **ninth** aspect, the present disclosure broadly comprises a method of estimating an off-therapy respiratory parameter of a patient during therapy, the method comprising: providing a flow of gases at a plurality of flow rates via a flow generator; receiving data indicative or representative of one or more properties the flow of gases provided by the flow generator at each of the plurality of flow rates; estimating or determining a respiratory parameter of the patient at each of the plurality of flow rates based at least on the data received; and estimating the off-therapy respiratory parameter of the patient using a model based at least on the estimated or determined respiratory parameter determined at each of the plurality of flow rates, and determining a difference between at least the estimated or determined respiratory rates/parameters determined at each of the plurality of flow rates.

In a **tenth** aspect, the present disclosure relates to an electronically-implemented method comprising software code or coded instructions that are executable or implemented by a computer, processor, or controller to carry out any one or more of the methods or aspects described above.

In an **eleventh** aspect, the present disclosure broadly comprises a non-transitory computer-readable medium having stored thereon computer executable instructions that, when executed on a processing device or devices, cause the processing device or devices to perform or execute any one or more of the methods or aspects described above.

The **fourth, fifth, sixth, seventh, eighth, ninth, tenth, and eleventh** aspects may comprise any one or more of the features of the **first, second, or third** aspects described above.

In a **twelfth aspect**, the present disclosure broadly comprises a respiratory therapy apparatus configured to provide a flow of gases to a user, comprising: a flow generator configured to provide a flow of gases according to one or more therapy parameters, the one or more therapy parameters comprising at least an operating flow rate; one or more sensors each configured to generate data indicative or representative of one or more properties of the flow of gases; a display for showing information to a user; and a controller, wherein the controller is configured to: receive the data indicative or representative of one or more

properties of the flow of gases from the one or more sensors, determine or receive an indication of an off therapy respiratory parameter of the patient, the indication of the off therapy respiratory parameter determined based at least in part on the data indicative or representative of one or more properties of the flow of gases, and cause the display to show one or more graphical displays, wherein the or each graphical display is based on the indication of an off therapy respiratory parameter of the patient.

In a configuration, a graphical display is configured to display the indication of an off therapy respiratory parameter to a user.

In a configuration, a graphical display screen is configured to display one or more off-therapy respiratory parameter based at least in part on the indication of an off therapy respiratory parameter over time.

In a configuration, a graphical display is configured to display a notification, alert, or suggestion based on the indication of an off therapy respiratory parameter.

In a configuration, a graphical display is configured to display a suggestion for changes to the therapy settings of the respiratory therapy apparatus based on the indication of an off therapy respiratory parameter.

In a **thirteenth aspect**, the present disclosure broadly respiratory therapy apparatus configured to provide a flow of gases to a user, comprising: a flow generator configured to provide a flow of gases according to one or more therapy parameters, the one or more therapy parameters comprising at least an operating flow rate; one or more sensors each configured to generate data indicative or representative of one or more properties of the flow of gases; and a controller, wherein the controller is configured to: receive the data indicative or representative of one or more properties of the flow of gases from the one or more sensors, determine or receive an indication of an off-therapy respiratory parameter of the patient, the indication of the off-therapy respiratory parameter determined based at least in part on the data indicative or representative of one or more properties of the flow of

gases, and adjust one or more of the therapy parameters based on the indication of an off-therapy respiratory parameter of the patient.

In a configuration, the controller is configured to determine an indication of an off-therapy respiratory parameter of the patient by controlling the flow generator to provide a flow of gases at the plurality of flow rates, the plurality of flow rates comprising least at an operating flow rate and one or more intermediate flow rates; estimating or determining a respiratory parameter of the patient at each of the plurality of flow rates based at least in part on the flow parameter data received; and estimating an off-therapy respiratory parameter of the patient based at least in part on the estimated or determined respiratory parameter determined at each of the plurality of flow rates.

In a configuration, the one or more of the therapy parameters comprise a flow rate setting and/or an FiO₂ setting.

The **twelfth** and **thirteenth** aspects may comprise any one or more of the features of the **first**, **second**, or **third** aspects described above.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects, and advantages of the present disclosure are described with reference to the drawings of certain embodiments, which are intended to schematically illustrate certain embodiments and not to limit the disclosure.

Figure 1 shows schematically a respiratory system configured to provide a respiratory therapy to a patient.

Figure 2 illustrates a block diagram of a control system interacting with and/or providing control and direction to components of a respiratory system.

Figure 3 illustrates a block diagram of an example controller.

Figure 4 illustrates an example block diagram for determining a respiratory rate from a gases flow parameter.

Figure 5 illustrates an example flow chart of using outputs from an algorithm to determine a respiratory rate estimate.

Figure 6 illustrates a summary flow diagram of an example of a breathing parameter determination process.

Figure 7 illustrates an example flow chart of estimating of an off-therapy respiratory parameter using flow parameter data.

Figure 8 illustrates an example flow chart of estimating of an off-therapy respiratory parameter using flow parameter data.

Figure 9 illustrates an example flow chart of estimating of an off-therapy respiratory rate using flow parameter data.

Figure 10 illustrates an example flow chart of estimating of an off-therapy respiratory rate using flow parameter data.

DETAILED DESCRIPTION

Although certain examples are described below, those of skill in the art will appreciate that the disclosure extends beyond the specifically disclosed examples and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the disclosure herein disclosed should not be limited by any particular examples described below.

1. Overview of Example Respiratory Apparatus

Examples of the methods and processes of estimating off-therapy respiratory parameters will be described in the context of an example respiratory apparatus or breathing assistance apparatus (these terms are used interchangeably) 100 that is configured or operable to provide nasal high flow therapy via an unsealed patient interface. This is intended as a non-limiting example. It will be appreciated that the methods and processes may be applied to other respiratory apparatus and/or to other modes of operation and/or modes of therapy delivered by such apparatus.

A schematic representation of the example respiratory system 10 is provided in Figure 1. The respiratory system 10 includes a respiratory apparatus (generally shown in the dashed box 60) having a flow generator 50B and a controller 19. The respiratory apparatus 60 may further include a humidifier 52. The respiratory apparatus 60 may include an integrated flow generator 50B and humidifier 52 (e.g., the flow generator 50B and the humidifier 52 may be arranged in the same housing of the respiratory apparatus 60) as illustrated in Figure 1, or

the humidifier 52 may be in a separate housing. A delivery conduit 16 and a patient interface 51 may be provided, as part of the respiratory system 10, to fluidly couple to the respiratory apparatus 60.

The controller 19 may include one or more control systems, e.g., control system 920 of Figure 2 to be described further below, and/or may have a configuration similar to the controller 600 of Figure 3 to be described further below. The controller 19 may have controller function as described further below in the context of the control system 920 of Figure 2 or the controller 600 of Figure 3.

The respiratory system 10 comprises a flow source 50 for providing a high flow gas 31 such as air, oxygen, air blended with oxygen, or a mix of air and/or oxygen and one or more other gases. The breathing assistance apparatus 60 can have a connection for coupling to a flow source. As such, the flow source might be considered to form part of the apparatus 60 or be separate to it, depending on context, or even part of the flow source forms part of the apparatus 60, and part of the flow source falls outside of the apparatus 60. In short, depending on the configuration (some components may be optional), the system 10 can include a combination of components selected from the following:

- a flow source,
- humidifier for humidifying the gas-flow,
- conduit (e.g., dry line or heated breathing tube),
- patient interface,
- non-return valve,
- filter.

The system 10, including the apparatus 60, will now be described in more detail.

The flow source could be an in-wall supply of oxygen, a tank of oxygen 50A, a tank of other gas and/or a high flow apparatus with a flow generator 50B. Figure 1 shows a flow source 50 with a flow generator 50B, with an optional air inlet 50C and optional connection to an oxygen (O₂) source (such as tank or O₂ generator) 50A via a shut off valve and/or regulator and/or other gas flow control 50D, but this is just one option. The flow generator 50B can

control flows delivered to the user or patient 56 using one or more valves, or optionally the flow generator 50B can comprise a blower. The flow source 50 could be one or a combination of a flow generator 50B, O₂ source 50A, air source 50C as described. The flow source 50 is shown as part of the apparatus 60, although in the case of an external oxygen tank or in-wall source, it may be considered a separate component, in which case the apparatus 60 has a connection port to connect to such flow source. The flow source 50 provides a (preferably high) flow of gas that can be delivered to a patient 56 via a delivery conduit 16, and a patient interface 51.

The patient interface 51 may be an unsealed (non-sealing) interface (for example, when used in high flow therapy) such as a non-sealing nasal cannula. In some embodiments, the patient interface 51 is a non-sealing patient interface which would, for example, help to prevent barotrauma (e.g., tissue damage to the lungs or other organs of the respiratory system due to difference in pressure relative to the atmosphere). The patient interface 51 may be a nasal cannula with a manifold and nasal prongs, or any other suitable types of non-sealing patient interface. The flow source 50 could provide a base gas flow rate of between, e.g., 0.5 litres/min and 375 litres/min, or any range within that range, or even ranges with higher or lower limits. Details of the ranges and nature of flow rates will be described later.

A humidifier 52 can optionally be provided between the flow source 50 and the patient 56 to provide humidification of the delivered gas. One or more sensors 53A, 53B, 53C, 53D such as flow, oxygen fraction, pressure, humidity, temperature or other sensors can be placed throughout the system 10 and/or at, on or near the patient 56. Alternatively, or additionally, sensors from which such parameters can be derived could be used. In addition, or alternatively, the sensors 53A-53D can be one or more physiological sensors for sensing patient physiological parameters such as, heart rate, oxygen saturation, partial pressure of oxygen in the blood, respiratory rate, partial pressure of carbon dioxide (CO₂) in the blood. Alternatively, or additionally, sensors from which such parameters can be derived could be used. Other patient sensors could comprise EEG sensors, torso bands to detect breathing, and any other suitable sensors. In some configurations the humidifier 52 may be optional, or it may be preferred due to the advantages of humidified gases helping to maintain the condition of the airways and to provide comfort to the patient. One or more of the sensors

53A-53D might form part of the apparatus 60, or be external thereto, with the apparatus 60 having inputs for any external sensors. The sensors (e.g., 53A-53D) can be coupled to or send their output to a controller 19.

In some configurations, the respiratory system 10 can include a sensor 14 for measuring the oxygen fraction of air the patient 56 inspires. In some examples, the sensor 14 can be placed on the patient interface 51, to measure or otherwise determine the fraction of oxygen proximate (at/near/close to) the patient's mouth and/or nose. In some configurations, the output from the sensor 14 is sent to the controller 19 to assist control of the respiratory apparatus 60 to alter operation accordingly. The controller 19 is coupled to the flow source 50, humidifier 52 and sensor 14. In some configurations, the controller 19 controls these and other aspects of the respiratory apparatus 60 and the respiratory system 10 as described herein. In some examples, the controller 19 can operate the flow source 50 to provide the delivered flow of gas 31 at a desired flow rate high enough to meet or exceed a user's (i.e., patient's) inspiratory demand. The flow rate provided is sufficient that ambient gases are not entrained as the user (i.e., patient) 56 inspires. In some configurations, the sensor 14 can convey measurements of oxygen fraction at the patient mouth and/or nose to a user, who can input the information to the respiratory apparatus 60 / controller 19.

An optional non-return valve 23 may be provided in the breathing conduit 16. A filter or filters may be provided at the air inlet 50C and/or inlets to the flow generator 50B to filter the incoming gases before they are pressurized into a high flow gas 31 by the flow generator 50B.

The breathing assistance system 10 could be an integrated or a separate component-based arrangement. In some configurations, the system 10 and/or the apparatus 60 could be a modular arrangement of components. Furthermore, the system 10 and/or the apparatus 60 may just comprise some of the components shown, not necessarily all are essential. The conduit 16 and patient interface 51 are separate from the respiratory apparatus 60. Breathing assistance apparatus will be broadly considered herein to comprise anything that provides a flow rate of gas to a patient. The breathing assistance apparatus can be part of a respiratory

system. Some such apparatus and systems may include a detection system that can be used to determine if the flow rate of gas meets inspiratory demand.

The respiratory apparatus 60 can include a main device housing (not shown). The housing can contain the flow generator 50B that can be in the form of a motor/impeller arrangement, an optional humidifier or humidification chamber 52, a controller 19, and an input/output (I/O) user interface 54. The user interface 54 can include a display and input device(s) such as button(s), a touch screen (e.g., an LCD touch screen), a combination of a touch screen and button(s), or the like. The controller 19 can include one or more hardware and/or software processors and can be configured or programmed to control the components of the respiratory apparatus 60, including but not limited to operating the flow generator 50B to create a flow of gases 31 for delivery to a patient 56, operating the humidifier or humidification chamber 52 (if present) to humidify and/or heat the gases flow 31, receiving user input from the user interface 54 for reconfiguration and/or user-defined operation of the respiratory apparatus 60, and outputting information (for example on the display) to the user. The user can be a patient, healthcare professional, or others.

In one configuration, the user interface 54 of the respiratory apparatus 60 may comprise a removable display screen or touch screen.

With continued reference to Figure 1, a patient breathing conduit 16 can be coupled to a gases flow outlet (gases outlet or patient outlet port) 21 in the main device housing of the respiratory apparatus 60, and be coupled to a patient interface 51, such as a non-sealing interface like a nasal cannula with a manifold and nasal prongs. The patient breathing conduit 16 can also be a tracheostomy interface, or other unsealed interfaces.

The gases flow 31 can be generated by the flow generator 50B, and may be humidified, before being delivered to the patient 56 via the patient breathing conduit 16 through the patient interface 51. The controller 19 can control the flow generator 50B to generate a gases flow 31 of a desired flow rate, and/or one or more valves to control mixing of air and oxygen or other breathable gas. The controller 19 can control a heating element in or associated with the humidification chamber 52, if present, to heat the gases to a desired temperature that

achieves a desired level of temperature and/or humidity for delivery to the patient 56. The patient breathing conduit 16 can have a heating element, such as a heater wire, to heat gases flow 31 passing through to the patient 56. The heating element can also be under the control of the controller 19.

The humidifier 52 of the apparatus 60 is configured to combine or introduce humidity with or into the gases flow 31. Various humidifier 52 configurations may be employed. In one configuration, the humidifier 52 can comprise a humidification chamber that is removable. For example, the humidification chamber may be partially or entirely removed or disconnected from the flow path and/or apparatus 60. By way of example, the humidification chamber may be removed for refilling, cleaning, replacement and/or repair for example. In one configuration, the humidification chamber may be received and retained by or within a humidification compartment or bay of the apparatus 60, or may otherwise couple onto or within the housing of the apparatus 60.

The humidification chamber of the humidifier 52 may comprise a gases inlet and a gases outlet to enable connection into the gases flow path of the apparatus 60. For example, the flow of gases 31 from the flow generator 50B is received into the humidification chamber via its gases inlet and exits the chamber via its gases outlet, after being heated and/or humidified.

The humidification chamber contains or receives a volume of liquid, typically water or similar. In operation, the liquid in the humidification chamber is controllably heated by one or more heaters or heating elements associated with the chamber to generate water vapour or steam to increase the humidity of the gases flowing through the chamber.

In one configuration, the humidifier 52 is a pass-over humidifier. In another configuration, the humidifier 52 may be a non-pass-over humidifier.

In one configuration, the humidifier 52 may comprise a heater plate, for example, associated or within a humidification bay that the chamber sits on for heating. The chamber may be

provided with a heat transfer surface, e.g., a metal insert, plate or similar, in the base or other surface of the chamber that interfaces or engages with the heater plate of the humidifier 52.

In another configuration, the humidification chamber may comprise an internal heater or heater elements inside or within the chamber. The internal heater or heater elements may be integrally mounted or provided inside the chamber, or may be removable from the chamber.

The humidification chamber may be any suitable shape and/or size. The location, number, size, and/or shape of the gases inlet and gases outlet of the chamber may be varied as required. In one configuration, the humidification chamber may have a base surface, one or more side walls extending up from the base surface, and an upper or top surface. In one configuration, the gases inlet and gases outlet may be positioned on the same side of the chamber. In another configuration, the gases inlet and gases outlet may be on different surfaces of the chamber, such as on opposite sides or locations, or other different locations.

In some configurations, the gases inlet and gases outlet may have parallel flow axes. In some configurations, the gases inlet and gases outlet may be positioned at the same height on the chamber.

The system 10, including the apparatus 60, can use ultrasonic transducer(s), flow sensor(s) such as a thermistor flow sensor, pressure sensor(s), temperature sensor(s), humidity sensor(s), or other sensors, in communication with the controller 19, to monitor characteristics of the gases flow 31 and/or operate the apparatus 60 in a manner that provides suitable therapy. The gases flow characteristics can include gases concentration, flow rate, pressure, temperature, humidity, or others. The sensors 53A, 53B, 53C, 53D, 14, such as pressure, temperature, humidity, and/or flow sensors, can be placed in various locations in the main device housing, the patient conduit 16, and/or the patient interface 51. The controller 19 can receive output from the sensors 53A, 53B, 53C, 53D, 14 to assist it in operating the respiratory apparatus 60 in a manner that provides suitable therapy, such as to determine a suitable target temperature, flow rate, and/or pressure of the gases flow. Providing suitable therapy can include meeting or exceeding a patient's inspiratory demand. In the illustrated embodiment, sensors 53A, 53B, and 53C are positioned in the housing of

the apparatus 60, sensor 53D in the patient conduit 16, and sensor 14 in the patient interface 51.

The respiratory system 10 may include a sensor arrangement or a sensor module. The sensor arrangement or module may include a plurality of sensor types. The respiratory system 10 may include one or more of a flow (or flow rate) sensor, a pressure sensor, a temperature sensor, a humidity sensor and an oxygen (O₂) sensor. The O₂ sensor may be an ultrasonic sensor. An ultrasonic sensor may be positioned in line with the flow and hence can be used as a flow sensor in addition to the O₂ sensor. One non-limiting example of a flow rate sensor is a thermistor flow rate sensor as described in PCT Application Publication No. WO2018/052320, filed 3 September 2017, which is incorporated by reference herein in its entirety. Another non-limiting example of a flow rate sensor is an acoustic flow rate sensor as described in PCT Application Publication No. WO2017/095241, filed 2 December 2016, which is incorporated by reference herein in its entirety.

In some configurations, the gases flow rate may be measured using at least two different types of sensors. For example, a first type of sensor may include a thermistor flow rate sensor, and a second type of sensor may include an acoustic flow rate sensor. Readings from both the first and second types of sensors can be combined to determine a more accurate flow measurement. For example, a previously determined flow rate and one or more outputs from one of the types of sensor can be used to determine a predicted current flow rate. The predicted current flow rate can then be updated using one or more outputs from the other one of the first and second types of sensor, in order to calculate a final flow rate.

The apparatus 60 can include one or more communication modules to enable data communication or connection with one or more external devices or servers over a data or communication link or data network, whether wired, wireless or a combination thereof. In one configuration, for example, the apparatus 60 can include a wireless data transmitter and/or receiver, or a transceiver 15 to enable the controller 19 to receive data signals in a wireless manner from the operation sensors and/or to control the various components of the apparatus 60. The transceiver 15 or data transmitter and/or receiver module may have an antenna 15a as shown. In one example, the transceiver 15 may comprise a Wi-Fi modem.

Additionally, or alternatively, the data transmitter and/or receiver 15 can deliver data to a remote patient management system (i.e., a remote server) or enable remote control of the apparatus 60. The apparatus 60 can include a wired connection, for example, using cables or wires, to enable the controller 19 to receive data signals from the operation sensors and/or to control the various components of the apparatus 60. The apparatus 60 may comprise one or more wireless communication modules. For example, the apparatus 60 may comprise a cellular communication module such as for example a 3G, 4G or 5G module. The module 15 may be or may comprise a modem that enables the apparatus 60 to communicate with a remote patient management system (not illustrated in the figures) using an appropriate communication network. The remote management system may comprise a single server or multiple servers or multiple computing devices implemented in a cloud computing network. The communication may be two-way communication between the apparatus 60 and a patient management system (e.g., a server) or other remote system. The apparatus 60 may also comprise other wireless communication modules such as, for example, a Bluetooth module and/or a Wi-Fi module. The Bluetooth and/or WiFi module allow the apparatus 60 to wirelessly send information to another device such as, for example, a smartphone or tablet or operate over a LAN (local area network) or Wireless LAN (WLAN). The apparatus 60 may additionally, or alternatively, comprise a Near Field Communication (NFC) module to allow for data transfer and/or data communication.

For example, data representing determined or calculated work of breathing (WOB) indicators may be communicated to a remote patient management system (i.e., a remote server). The remote patient management system may be a single server or a network of servers or a cloud computing system or other suitable architecture for operating a remote patient management system. The remote patient management system (i.e., a remote server) further includes memory for storing received data and various software applications or services that are executed to perform multiple functions. Then, for example, the remote patient management system (i.e., remote server) may communicate information or instructions to the apparatus 60, as part of the system 10, at least in part dependent on the data received. For example, the nature of the data received may trigger the remote server (or a software application running on the remote server) to communicate an alert, alarm, or notification to the apparatus 60. The remote patient management system may further store the received data for access by an

authorised party such as a clinician or the patient or another authorized party. The remote patient management system may further be configured to generate reports in response to a request from an authorized party, and the work of breathing data may be included into the generated reports. The reports may further comprise other data or patient breathing parameters, e.g., respiratory rate or SpO₂ and/or device parameters, e.g., flow rate, humidity level.

The respiratory apparatus 60 may comprise a high flow therapy apparatus. High flow therapy as discussed herein is intended to be given its typical ordinary meaning, as understood by a person of skill in the art, which generally refers to a respiratory system, having a high flow therapy apparatus, delivering a targeted flow of humidified respiratory gases via an intentionally unsealed patient interface with flow rates generally intended to meet or exceed inspiratory flow of a user. Typical patient interfaces include, but are not limited to, a nasal or tracheal patient interface. Typical flow rates for adults often range from, but are not limited to, about fifteen litres per minute (15 litres/min) to about sixty litres per minute (60 litres/min) or greater. Typical flow rates for paediatric users (such as neonates, infants and children) often range from, but are not limited to, about one litre per minute per kilogram of user weight to about three litres per minute per kilogram of user weight or greater.

High flow therapy can also optionally include gas mixture compositions including supplemental oxygen and/or administration of therapeutic medicaments.

High flow therapy is often referred to as nasal high flow (NHF), humidified high flow nasal cannula (HHFNC), high flow nasal oxygen (HFNO), high flow therapy (HFT), or tracheal high flow (THF), among other common names. For example, in some configurations, for an adult patient, 'high flow therapy' may refer to the delivery of gases to a patient at a flow rate of greater than or equal to about 10 litres per minute (10 LPM), such as between about 10 LPM and about 100 LPM, or between about 15 LPM and about 95 LPM, or between about 20 LPM and about 90 LPM, or between about 25 LPM and about 85 LPM, or between about 30 LPM and about 80 LPM, or between about 35 LPM and about 75 LPM, or between about 40 LPM and about 70 LPM, or between about 45 LPM and about 65 LPM, or between about 50 LPM and about 60 LPM. In some configurations, for a neonatal, infant, or child patient, 'high flow

therapy' may refer to the delivery of gases to a patient at a flow rate of greater than 1 LPM, such as between about 1 LPM and about 25 LPM, or between about 2 LPM and about 25 LPM, or between about 2 LPM and about 5 LPM, or between about 5 LPM and about 25 LPM, or between about 5 LPM and about 10 LPM, or between about 10 LPM and about 25 LPM, or between about 10 LPM and about 20 LPM, or between about 10 LPM and 15 LPM, or between about 20 LPM and 25 LPM. A high flow therapy apparatus with an adult patient, a neonatal, infant, or child patient, may deliver gases to the patient at a flow rate of between about 1 LPM and about 100 LPM, or at a flow rate in any of the sub-ranges outlined above.

High flow therapy can be effective in meeting or exceeding the patient's inspiratory demand, increasing oxygenation of the patient and/or reducing the work of breathing. Additionally, high flow therapy may generate a flushing effect in the nasopharynx such that the anatomical dead space of the upper airways is flushed by the high incoming gases flow. The flushing effect can create a reservoir of fresh gas available for each and every breath, while minimizing re-breathing of carbon dioxide, nitrogen, etc. High flow therapy can also increase expiratory time of the patient due to pressure during expiration. This in turn reduces the respiratory rate of the patient.

The flow rate may be set by a clinician to achieve flushing of the patient's upper airways and/or meet or exceed a patient's inspiratory demand and/or provide at least some of the advantages of high flow therapy (HFT) described herein. The flow rate may further be set to improve oxygenation and slowing of the respiratory rate of the patient, or otherwise reduce the respiratory effort of patient.

The patient interface for use in a high flow therapy can be a non-sealing interface to prevent barotrauma, which can include tissue damage to the lungs or other organs of the patient's respiratory system due to difference in pressure relative to the atmosphere. The patient interface can be a nasal cannula with a manifold and nasal prongs, and/or an unsealed tracheostomy interface, or any other suitable types of non-sealing patient interface.

The respiratory apparatus or device 60 can have air and oxygen (or alternative auxiliary gas) inlets in fluid communication with a motor of the respiratory apparatus 60 to enable the

motor to deliver air, oxygen (or alternative auxiliary gas), or a mixture thereof to the humidification chamber and thereby to the patient.

The respiratory apparatus 60 may include a connector arrangement with one or more connectors, for example, USB or other suitable connectors, for coupling of an alarm, a pulse oximetry port, and/or other suitable accessories.

The respiratory apparatus 60 may include an electrical connector through which mains electricity or battery power may be provided to power the respiratory apparatus 60. The respiratory apparatus 60 may further include a battery or an internal power source that can power the apparatus 60 for a set period of time if the mains are disconnected.

1.1 Control System

Figure 2 illustrates a block diagram 900 of an example control system 920 (which can, for example, be the controller 19 in Figure 1) that can detect patient conditions and control operation of the respiratory system including the gases source. The control system 920 can manage a flow rate of the gases flowing through the respiratory system as is the gases are delivered to a patient. For example, the control system 920 can increase or decrease the flow rate by controlling an output of a motor speed of the blower (hereinafter also referred to as a “blower motor”) 930 or an output of a valve 932 in a blender. The control system 920 can automatically determine a set value or a personalized value of the flow rate for a particular patient as discussed below. The flow rate can be optimized by the control system 920 to improve patient comfort and therapy.

The control system 920 can also generate audio and/or display/visual outputs 938, 939. For example, the flow therapy apparatus can include a display and/or an audio output device (e.g., speaker). The display can indicate to the physicians any warnings or alarms generated by the control system 920. The display can also indicate control parameters that can be adjusted by the physicians. For example, the control system 920 can automatically recommend a flow rate for a particular patient. The control system 920 can also determine a respiratory state of the patient, including but not limited to generating a respiratory rate of the patient, and send it to the display, which will be described in greater detail below.

The control system 920 can change heater control outputs to control one or more of the heating elements (for example, to maintain a temperature set point of the gases delivered to the patient). The control system 920 can also change the operation or duty cycle of the heating elements. The heater control outputs can include heater plate control output(s) 934 and heated breathing tube control output(s) 936.

The control system 920 can determine the outputs 930-939 based on one or more received inputs 901-916. The inputs 901-916 can correspond to sensor measurements received automatically by the controller 600 (shown in Figure 3). The control system 920 can receive sensor inputs including but not limited to temperature sensor(s) inputs 901, flow rate sensor(s) inputs 902, motor speed inputs 903, pressure sensor(s) inputs 904, gas(s) fraction sensor(s) inputs 905, humidity sensor(s) inputs 906, pulse oximeter (for example, SpO₂) sensor(s) inputs 907, stored or user parameter(s) 908, duty cycle or pulse width modulation (PWM) inputs 909, voltage(s) inputs 910, current(s) inputs 911, acoustic sensor(s) inputs 912, power(s) inputs 913, resistance(s) inputs 914, CO₂ sensor(s) inputs 915, and/or spirometer inputs 916. The control system 920 can receive inputs from the user or stored parameter values in a memory 624 (shown in Figure 3). The control system 920 can dynamically adjust flow rate for a patient over the time of their therapy. The control system 920 can continuously detect system parameters and patient parameters. A person of ordinary skill in the art will appreciate based on the disclosure herein that any other suitable inputs and/or outputs can be used with the control system 920.

1.2 Controller

Figure 3 illustrates a block diagram of an embodiment of a controller 600 (which can, for example, be the controller 19 in Figure 1). The controller 600 can include programming instructions for detection of input conditions and control of output conditions. The programming instructions can be stored in the memory 624 of the controller 600. The programming instructions can correspond to the methods, processes and functions described herein. The programming instructions can be executed by one or more hardware processors 622 of the controller 600. The programming instructions can be implemented in C, C++, JAVA, or any other suitable programming languages. Some or all of the portions of the programming instructions can be implemented in application specific circuitry 628 such as ASICs and FPGAs.

The controller 600 can also include circuits 628 for receiving sensor signals. The controller 600 can further include a display 630 for transmitting status of the patient and the respiratory assistance system. The display 630 can also show warnings and/or other alerts. The display 630 can be configured to display characteristics of sensed gas(es) in real time or otherwise. The controller 600 can also receive user inputs via the user interface such as display 630. The user interface can include button(s) and/or dial(s). The user interface can comprise a touch screen.

2. Examples of off-therapy respiratory parameter estimation processes

The methods and processes of estimating off-therapy respiratory parameters will be described in the context of the example respiratory apparatus 100 described above, which is configured or operable to provide nasal high flow therapy via an unsealed patient interface. As explained earlier, the methods and processes may also be applied to other respiratory apparatus and/or to other modes of operation and/or modes of therapy delivered by such apparatus.

2.1 Summary of off-therapy respiratory parameter estimation processes

Respiratory parameters of a patient, such as the patient's respiratory rate, may provide information on whether a patient's condition is worsening or improving. This is because respiratory parameters can be indicative of a patient's health condition or respiratory health condition. Generally speaking, patients with a chronic respiratory condition or respiratory system impairment due to an infection, disease, injury, etc. will exhibit abnormal respiratory parameters, such as high/higher respiratory rates. For example, in the cases of chronic obstructive pulmonary disease (COPD), bronchiectasis, or pulmonary emphysema, a common symptom of worsening condition is increased respiratory rate, which may be indicative of oxygenation difficulties or other underlying issues. Increased or increasing respiratory rate over a period of multiple days may be a sign of an oncoming exacerbation in these conditions, or the onset of a respiratory infection, for example. Further, for patients that have been recently treated for an acute respiratory condition and are still in recovery, a change in respiratory parameters (e.g., an increase in respiratory rate) can be an early sign of deterioration in the patient's condition which warrants attention.

Respiratory parameters may also provide information on when a patient has stabilised after being placed on or provided with respiratory therapy. Monitoring or determining respiratory parameters of the patient can thus aid in the control of operating parameters relating to the provision of respiratory therapy by a respiratory apparatus. An example of a respiratory therapy provided by a respiratory apparatus is high flow therapy (HFT). Respiratory parameters can also provide a means to identify optimal or otherwise acceptable operating parameters or therapy settings when a patient is receiving respiratory therapy. For example, operating parameters or therapy settings may relate to the flow rate provided by the respiratory apparatus, and/or the oxygen content/concentration of the gases flow provided to the patient (FdO_2 (fraction of delivered oxygen) or FiO_2), and/or the pressure provided by the respiratory apparatus, among other operating parameters or therapy settings.

The term 'respiratory parameter' as used in this specification and claims should be taken to include, unless the context suggests otherwise, a physiological parameter related to a patient's breathing or respiration. For example, it will be appreciated that breathing or respiration encompasses cycles of inspiration and expiration/inspiratory phases and expiratory phases. A respiratory parameter may be related to the timing and/or volume of a patient's breathing or respiration. As such, a respiratory parameter may relate to a respiratory timing parameter or a respiratory volume parameter. A respiratory parameter may be measurable by one or more sensors or otherwise able to be determined or estimated based on the output of one or more sensors. Examples of respiratory parameters include respiratory rate, inspiratory and/or expiratory times, or the ratio of inspiratory to expiratory phases (I:E ratio).

While the patient is receiving respiratory therapy, one or more of their respiratory parameters, such as their respiratory rate, may change significantly and may subsequently not provide an accurate indication of the condition of the patient. While it is a desirable outcome that respiratory therapy reduce or ameliorate breathing difficulties, it is an objective of the present disclosure to monitor the non-obfuscated or off-therapy respiratory parameters of chronic or post-acute care patients (for example in the home) in order to assess if there are changes in the patient's respiratory parameters, which can be used as an early sign of deterioration in the patient's condition, as discussed above. The change of the patient's one or more respiratory parameters (such as respiratory rate) is a typical response to respiratory therapy, especially high

flow therapy. High flow therapy generally has the effect of reducing the patient's work of breathing and/or respiratory rate. A reduction in the patient's work of breathing and/or respiratory rate may be a result of the increased respiratory (end-expiratory) pressure provided by high flow therapy, and/or the dead space clearance which typically occurs due to the high flows provided by high flow therapy, as described earlier. The provision of supplementary oxygen, which is sometimes included with high flow therapy, may also contribute to the reduction of the patient's work of breathing and/or respiratory rate.

As such, measuring or estimating one or more of the respiratory parameters of a patient while they are not receiving therapy and are at rest, which may be referred to as "off-therapy respiratory parameters", may also be useful in predicting the likelihood of, or potential for, degradation in or worsening of the patient's condition. Changes in one or more of a patient's off-therapy respiratory parameters can be indicative of an onset of a respiratory disease or infection, or a worsening of pre-existing chronic respiratory conditions. A decrease or at least stabilisation in an off-therapy respiratory parameter of a patient over time may be a good indicator of the patient's receptiveness to therapy, and that the configuration of the therapy device settings is suitable.

As noted above, it is an objective of the present disclosure to monitor the non-obfuscated or off-therapy respiratory parameters of chronic or post-acute care patients, for example in the home. However, the methods, apparatuses, and systems of the present disclosure may similarly be useful in the hospital context. When used in a hospital context, the present disclosure may, for example, help identify whether a patient can be safely taken off a respiratory therapy device or whether the flow rate setting provided can be safely reduced.

The phrase "off-therapy respiratory parameter", when used in this specification and claims, refers to a measurable or otherwise able to be estimated or approximated respiratory parameter of a patient when they are at rest, or in a resting state, and are not undergoing physical exertion, nor being provided with respiratory therapy. In some examples, off-therapy respiratory parameters may be parameters measured, estimated, or approximated while a patient is sleeping, but this need not always be the case.

The present disclosure relates to the estimation of one or more off-therapy respiratory parameters of the patient while air (or a mixture of gases comprising additional oxygen) is being supplied to the airways of the user using a respiratory therapy system. The estimation of the off-therapy respiratory parameter in the present disclosure thus relates to, while the patient is being supplied with air using a respiratory therapy system, estimating a respiratory parameter which would typically be measured when no flow is being generated by the flow generator, and they are at rest or in a resting state, and are not undergoing physical exertion.

Typically, measurement of off-therapy respiratory parameters of a patient relies on the use of external sensing devices and/or measurement procedures which occur when a patient is not receiving respiratory therapy. These external sensing devices and/or measurement procedures contribute to the overall 'hassle' for patients as they generally must undertake additional procedures in addition to using a respiratory therapy device. They may be required to undertake these procedures daily or even multiple times throughout each day, which may be perceived as an inconvenience and thus neglected. In addition, or even as an alternative, patients may be required to wear pieces of monitoring apparatus (such as chest bands and/or pulse oximeters) which could be uncomfortable or may be easy to forget to attach. If not attached, they may not measure the off-therapy respiratory parameters. In either case, the inconvenience or obtrusiveness associated with each approach can lead to unwelcome outcomes in which the patient may be discouraged from adhering with a respiratory therapy prescription involving the respiratory therapy device.

The present disclosure is therefore intended to provide the means to enable measurement of an off-therapy respiratory parameter or an estimation of a proxy of one or more of the off-therapy respiratory parameters of a patient in a seamless fashion, while they are using a respiratory therapy device. The present disclosure thus allows the estimation of the one or more off-therapy respiratory parameters of the patient without requiring any specific or additional actions or procedures to be performed, nor the use of extraneous sensors by the patient.

The estimates of the one or more off-therapy respiratory parameters of the patient provided by the present disclosure may help improve adherence to respiratory therapy/therapies by

facilitating better monitoring thereof and means to tailor therapy prescriptions to fit different patients. Estimating the off-therapy respiratory parameter(s) of the patient may also help to monitor the effect the respiratory therapy is having on the patient, and may also be used to determine if there is a change in the patient's respiratory condition. Furthermore, as discussed, the estimation of the patient's off-therapy respiratory parameter(s) while they are using a respiratory therapy device may improve compliance for patients as they do not have to perform additional actions or use additional sensors in order to measure their off-therapy respiratory parameter(s).

The methods, apparatuses, and systems of the present disclosure do not require additional sensors in order to estimate the off-therapy respiratory parameters of a patient. The presently disclosed methods, apparatuses, and systems use the sensors of a respiratory therapy device, alongside a controller, the controller being either of the respiratory therapy device or located elsewhere in a respiratory therapy system. Additionally, the present disclosure may lead to increases in the data coverage and/or reliability of the measurement or estimation of the patient's off-therapy respiratory parameter(s), for example — as there is no need to ensure external sensor(s) are worn correctly (or indeed, at all) by the patient. It can also provide for a like-for-like comparison of off-therapy respiratory parameter(s) taken of the patient whilst the patient is receiving therapy, or in similar states, as will be explained further.

The present disclosure also enables the off-therapy respiratory parameter(s) of the patient to be determined or estimated concurrent with the delivery of therapy. The patient's respiratory parameters, such as their respiration rate, may be highly variable throughout a day. For example, a patient's respiratory rate can be highly influenced by conscious breathing. As will be appreciated, when a patient is asleep or in another restful state, their breathing usually becomes more regular and consistent. It may also slow down. Whereas when a patient is awake, their breathing can vary dramatically, due to any sort of exertion, movement, or change in emotional state, for example.

As such, being able to estimate off-therapy respiratory parameter(s) of a patient concurrent with delivery of respiratory therapy may allow for a comparison with less confounding factors,

such as the time of the day, level of patient activity, etc. This can lead to improvements in the reliability of inferences made from the estimates of the respiratory parameter(s) which are used.

The respiratory rate of the patient is an important metric and can be indicative of the patient's respiratory effort. A higher than normal respiratory rate can indicate a patient having an adverse respiratory condition e.g., respiratory illness. Typically, when patients are receiving a respiratory therapy such as a nasal high flow therapy, their respiratory rate may be within a tolerable range by way of the therapy being provided. By estimating and monitoring the off-therapy respiratory rate of the patient, for example using the present disclosure, a clinician may be able to establish an indication of the health of the patient. The off-therapy respiratory rate of the patient may be collated over long periods of time e.g. over days, weeks, or months to determine an indication of the health or respiratory condition of the patient. The trend of the off-therapy respiratory rate over time can also be used to provide an indication of the health or respiratory condition of the patient. For example, a reducing off-therapy respiratory rate can indicate that the respiratory therapy being provided is effective for a particular patient.

This disclosure provides a method, and an apparatus and system for implementing a method, for reliably estimating one or more off-therapy respiratory parameters of a patient while they are undergoing high flow therapy delivered by a respiratory apparatus, using sensor data available from the respiratory apparatus and/or algorithms implemented thereon. The estimated off-therapy respiratory parameters may be used to enhance clinical decision making, patient outcomes, and/or operation of the respiratory apparatus to deliver improved high flow therapy.

This disclosure relates to methods and/or algorithms, and corresponding apparatuses and systems for implementing them, for estimating said one or more off-therapy respiratory parameters based at least partly on sensed flow parameter data indicative or representative of the flow of gases in the respiratory apparatus during use by a patient or user. By way of example, methods for estimating three different off-therapy respiratory parameters will be described later.

In the example methods, the various respiratory parameters are determined or calculated based at least partly on flow parameter data indicative or representative of the flow of gases

in the flow path of the respiratory apparatus. In an example configuration, the flow parameter data includes flow rate data indicative or representative of the flow rate of the flow of gases provided by the respiratory apparatus during respiratory therapy. In one example, the flow rate data may be a flow signal generated by a flow sensor or sensors provided or positioned in the flow path of the respiratory apparatus. The flow sensor or sensors may be provided in the flow path downstream of the flow generator of the respiratory apparatus. Fluctuations in the flow rate signal around typical human breathing frequencies will be observed when a patient is using the respiratory apparatus during respiratory therapy. The flow rate signal may be noisy, and in the example configurations, signal pre-processing may be applied to the raw flow signal generated by the flow sensor(s) to substantially filter or at least minimise the effects of noise. By analysing fluctuations in the pre-processed flow rate signal, various respiratory parameters of the patient can be determined or estimated while they are undergoing respiratory therapy with the respiratory apparatus.

In some example configurations, the flow parameter data used to determine or estimate the respiratory parameters may additionally or alternatively include pressure data indicative or representative of the flow of gases provided by the flow generator (e.g., the pressure at the outlet of the blower in the respiratory apparatus). The flow parameter data may further include motor speed data indicative of or representative of a speed the blower of the flow generator is functioning.

As will be described below, the present disclosure relates to the controlled adjustment of the operating flow rate to one or more intermediate flow rates, the measuring or estimating of one or more respiratory parameters at said intermediate flow rates, and one or more models/algorithms to determine the off-therapy respiratory parameter(s) of the patient based on said measured or estimated respiratory parameters at the intermediate flow rates, all with minimal disruption to the provision respiratory therapy.

The respiratory parameters intended by the present disclosure as relating to the patient and of which the off-therapy value can be estimated are those such as respiratory rate (RR), and inspiratory-expiratory time ratios (I:E ratio). Example configurations relating to these respiratory parameters are outlined, however it will be appreciated that off-therapy values of other

respiratory parameters are also capable of being estimated by the methods outlined below. Further, it will be appreciated that further respiratory parameters which are derivatives of any of the above-mentioned respiratory parameters may also be estimated. These derivative respiratory parameters may be determined or estimated using the respiratory parameters mentioned above. For example, derivative respiratory parameters may include: inspiratory time, or expiratory time, or total respiration time. These derivative respiratory parameters may be determined based on an estimated off-therapy respiratory rate or I:E ratio.

The respiratory parameters intended to have their off-therapy values estimated using the present method(s) are those which are able to be measured or determined at intermediate or sub-therapeutic flow rates and which could then be utilised to predict or extrapolate the off-therapy values.

As will be seen, in these example configurations, there are some common steps to estimating the off-therapy values for all the example respiratory parameters, which will be outlined below.

The methods and/or algorithms for estimating off-therapy respiratory parameters may be executed or implemented on any suitable controller or processor. In the example configuration, the methods and/or algorithms for estimating the off therapy respiratory parameters may be executed or implemented on the main or primary controller of the respiratory apparatus. As explained above, the main controller of the respiratory apparatus is in electrical or data communication with at least the flow and/or pressure sensors located in the respiratory apparatus main housing, breathing conduit, and/or patient interface. In some example configurations, pressure sensing lines may feed pressure samples from a patient interface to a pressure sensor or sensors located in the main housing of the respiratory apparatus.

2.2 Examples of determining respiratory parameters

Example methods or algorithms for determining or estimating two example respiratory parameters using the respiratory therapy device will now be discussed briefly.

2.2.1 First example respiratory parameter – Determining respiratory rate

A first example method or algorithm for determining or estimating a first example respiratory parameter will now be described. The first example respiratory parameter is indicative of the respiratory rate of the patient.

Respiratory rate can be an important indicator of patient condition. An abnormal respiratory rate has been shown to be a predictor of respiratory conditions and/or respiratory disease in a patient, and in some circumstances other serious events such as cardiac arrests and escalation to high levels of care. Respiratory rate can thus provide an indication of deterioration or an improvement in patient condition. Respiratory rate may also be related to the work of breathing of a patient.

Changes in the respiratory condition of a patient can quickly manifest as changes in respiratory rate. When a patient's condition worsens, their respiratory rate may increase. For example, the efficiency of gas exchange in the lungs may decrease as a respiratory condition worsens (e.g., as a COPD-related lung infection progresses), causing blood oxygen levels to decrease concurrently and triggering a sustained increase in respiratory rate as the patient tries to increase their minute ventilation to maintain normal blood oxygen levels. In this way, respiratory rate responds relatively quickly to a change in the patient's condition when compared with other measurable patient parameters such as peripheral oxygen saturation (SpO_2), which may typically be measured by an external pulse oximeter.

A patient's respiratory rate may be affected by other factors; for example, increased physical activity is likely to increase respiratory rate. However, patients receiving respiratory therapy, such as high flow therapy, are generally stationary and at rest, minimising other potential causes of respiratory rate changes.

More details of a method of determining or estimating a patient's respiratory rate are described in PCT Application Publication No. WO2019/102384A1, filed 22 November 2018, which is incorporated by reference herein in its entirety.

Figure 4 illustrates an example process for determining or estimating the patient's respiratory rate. A sensor output 2202 from a sensor configured for measuring a gases flow parameter can be fed into a signal processing algorithm 2204. The sensor can be located in, at least partially in, or outside of the gases flow path. The gases flow parameter can vary with the patient's breathing. The gases flow parameter can be the flow rate, pressure, oxygen or

carbon dioxide data (e.g., concentration of the gas within the gases flow), or others. The controller or processor(s) can run the signal processing algorithm 2204 to process the signal output 2202 and measure the gases flow parameter. A gases flow parameter signal 2206 can be fed into a signal analysis algorithm 2008.

The signal analysis algorithm 2008 can comprise a frequency analysis algorithm for a discrete time series. The frequency analysis algorithm can include a discrete Fourier transform (DFT) step. The discrete Fourier transform takes discrete time series data and converts it into a series of complex numbers which contains frequency, magnitude and phase information. The basic form of the DFT is:

$$X_k = \sum_{n=0}^{N-1} x_n \cdot e^{\frac{-i2\pi kn}{N}}$$

where X_k is the output series of complex numbers, x_n is the input series (also a series of complex numbers), N is a discrete number representing the number of data points in the input time series data x_n and k is the frequency of interest. By determining the modulus or absolute value of each complex number in the output series X_k , it is possible to extract the magnitude at each frequency. The magnitude represents the strength of the corresponding frequency component in the evaluated time series.

The time between data points limits the resolution of the frequencies within the range. In order to be able to confidently detect a frequency within a data set, the sampling frequency has to be at least twice the frequency of interest, i.e., the Nyquist frequency. This frequency should be at least as high as any frequency component that may need to be detected and analysed. The processes described herein can require measuring patient breathing at least as high as 60 breaths per minute, or 1 Hz, which requires a sampling rate of at least 2 Hz, or a sampling period of 500 ms per sample. The sampling rate can also be higher than twice the maximum detectable frequency that is to be measured in order to provide a buffer.

However, higher sampling rates result in more data points to be processed, which will be more computationally demanding. The sampling rate may also be limited by the rate at which the sensor can deliver data. For example, if using the flow rate as the gases flow

parameter, the thermistor sensor may be able to provide a data point as fast as every 14 ms, or at a frequency of 71.4 Hz.

To balance the need for confidence that the patient's respiratory rate is detected and the need to prevent the sampling rate from being too high, the sampling rate of the signal analysis algorithm 2208 can be between about 14 ms (71.4 Hz) and about 500 ms (2 Hz), or between about 20 ms (50 Hz) and about 400 ms (2.5 Hz), or between about 25 ms (40 Hz) and about 333 ms (3 Hz), or between about 40 ms (25 Hz) and about 250 ms (4 Hz), or between about 50 ms (20 Hz) and about 200 ms (5 Hz), or about 100 ms (10 Hz).

A dominant frequency as determined by the signal analysis algorithm 2208 from the output series can be the respiratory rate. The dominant frequency may be the frequency that has the greatest magnitude. As patient breathing activity will often be the most significant contributor to variations in the gases flow parameter, as compared to other factors that may affect the gases flow parameter, the dominant frequency can be assumed to correspond to the patient's respiratory rate. The exception to this is that, as described above, in configurations using an absolute value of the gases flow parameter instead of fluctuations from an average or target, the frequency component appearing at 0 Hz is ignored. The large magnitude at 0 Hz represents the average value of the gases flow parameter rather than the respiratory rate.

During the frequency analysis using the signal analysis algorithm 2208, the magnitudes of various frequency components are calculated from the data, each of which represent the strength of each frequency component in the data. The dominant frequency, or the frequency component that has the greatest magnitude, as determined by the algorithm 2208, is taken to be the respiratory rate 2210.

As shown in Figure 5, in some configurations that implement the frequency analysis algorithm, at each iteration of the algorithm, the controller can receive the magnitudes output from the algorithm at step 2302. At step 2304, the controller can identify local maxima of the magnitudes output by the frequency analysis algorithm. The local maxima are defined as frequency component magnitudes that are greater than the magnitudes of neighbouring

frequencies, and which are a sufficient distance from any larger local maxima. The controller can identify two or more (such as two, three, four, five, six or more) of the largest local maxima at each iteration of the algorithm.

Following the identification of the local maxima, the controller can apply a filter to each of the magnitudes of the two or more local maxima. To apply the filter, at decision step 2306, the controller identifies whether the frequency of any one of the local maxima is close to the frequency of one of the two or more local maxima from the previous iteration. Each of the latest local maxima are compared individually with each of the previous local maxima to determine whether there is a match. If one of the local maxima is close to (such as being substantially the same as or within a predetermined distance from) one of the previous local maxima, the filter uses the previous filtered magnitude value of the previous local maximum and the magnitude of the latest local maximum when determining the filtered frequency of the latest local maximum at step 2308. The latest local maximum being close to the previous local maximum can indicate that the latest local maximum is caused by the same waveform as the previous local maxima. If one of the local maxima is not close to any one of the previous local maxima, the controller starts the filtered magnitude of the new local maximum at zero (that is, assuming a zero value for the filtered magnitude of the previous local maximum) and applies the filter to the latest local maximum to obtain the filtered magnitude for the local maximum at step 2310. When one of the local maxima is not close to any of the previous local maxima, it is assumed that the latest local maximum is caused by a new waveform.

Once the filtered magnitudes for all the latest local maxima have been determined, at step 2312, the controller selects the highest value of the two to five filtered magnitudes. The frequency associated with the highest filtered magnitude value is assumed to be the most indicative of the respiratory rate of the patient. Due to the filtering described above, this method can allow the controller to ignore short term high amplitude signals, as these are unlikely to correspond to the patient's breathing and may instead be caused by transient behaviours such as coughing.

At step 2314, the controller can apply another filter to the chosen frequency (above) over time to generate a filtered respiratory rate of the patient. At each iteration of the algorithm, the filtered respiratory rate is updated using the latest frequency selected. The filter at step 2314 can also weight frequency values by the magnitude of the frequency component selected from the frequency analysis algorithm, such that the estimation of respiratory rate is updated more quickly when the breathing signal is stronger.

2.2.2 Second example respiratory parameter – Determining I:E ratio

A second example method or algorithm for determining or estimating a second example respiratory parameter will now be described. The second example respiratory parameter is indicative of the ratio of the inspiratory portion of the patient's respiration to the total respiration time or the expiratory portion of the patient's respiration, commonly referred to as the 'I:E ratio'.

More details of a method of determining or estimating a patient's I:E ratio are described in PCT Application Publication No. WO 2022/167982 A1, filed 04 February 2022, which is incorporated by reference herein in its entirety.

Referring to Figure 6, an example process 700 for determining or estimating the patient's I:E ratio is shown. The algorithm 700 operates or executes during operation of the respiratory apparatus 10, i.e., when it is delivering high flow therapy (or other forms of respiratory therapy) to a patient.

At step 701, the algorithm 700 receives or retrieves flow parameter data such as, but not limited to, a 'raw' flow rate signal or flow rate data — e.g., from one or more flow rate sensors of the respiratory apparatus, representing or indicative of the flow rate of the flow of gases or gases stream delivered to the patient. In this example, the algorithm operates continuously on new flow rate data as it arrives and processes the arriving data in the following manner.

At step 702, the raw flow rate data is pre-processed, e.g., filtered or otherwise processed, to remove unwanted signal components, such as those associated with the flow generator motor. The output of the pre-processing is a signal representative or indicative of patient breathing

data (with some residual noise components). In one configuration, the pre-processed signal may be in the form of flow parameter variation data. The flow parameter variation data may comprise a plurality of datapoints. Each datapoint may be a measure of the variation or deviation of the flow parameter from an average or a target value, such that the flow parameter variation data captures behaviour of the flow parameter attributable to patient breathing. Optionally, this pre-processing step 702 may comprise a preliminary stage of assessing the quality of the incoming raw flow rate data prior to further pre-processing. For example, good quality raw flow rate data may be further pre-processed into the flow parameter variation data and passed to the next step, but poor-quality data may be discarded.

At step 703, the pre-processed flow parameter variation data is processed to determine or calculate a ratio of the inspiratory time and/or expiratory time to the total respiratory time. The breathing parameter ratio may optionally be calculated as a rolling average by continuously summing and averaging pre-processed flow parameter variation datapoints. The ratio may be summed and stored. The stored rolling average of the breathing parameter ratio may be presented on a display (e.g., a graphical user interface of the apparatus).

A breathing parameter value (m_+) may be generated that represents or is indicative of whether the patient is currently inspiring or expiring. The breathing parameter value (m_+) can be a Boolean value or truth value that changes depending on the state of the patient's breathing, i.e., whether they are inspiring or expiring. In this example configuration, the breathing parameter value (m_+) is a Boolean value that represents or is indicative of whether the patient is currently inspiring. For example, in this configuration, the controller is configured to assign a '1' value if the patient is inspiring — i.e., (m_+) is 1 for patient inspiration — and the controller is configured to assign a '0' when the patient is expiring — i.e., (m_+) is 0 for patient expiration. The determination as to whether a patient is inspiring or expiring may be based on analysis of a fitted function or line to the flow parameter variation data, or directly from the flow parameter variation data, depending on the configuration. The controller may determine that the patient is inspiring or expiring at a given time-point in the data by comparing the corresponding datapoint of the fitted function or line to a threshold (which may be zero — i.e., if the datapoint on the line is above zero the patient is inspiring; below zero the patient is expiring — or another

value). The data processing, and associated criteria or threshold(s), applied to determine the breathing parameter value will be explained in further detail later.

The algorithm calculates a rolling or running average or filtered average of the breathing parameter value (m_+) calculated from the prior steps. This rolling average value is representative or indicative of the current breathing parameter ratio ($\frac{T_i}{T_{tot}}$) of the inspiration time (T_i) to the total respiration time (T_{tot}) of the patient's breathing or respiration cycle. Optionally, in some configurations, this step may comprise or involve one or more additional processes or processing stages. As will be explained further, such optional additional stages may, for example, include: noise correction and/or noise cleaning and/or noise filtering processes; and/or signal or data quality determination or processing.

At step 704, the algorithm 700 may optionally either receive data indicative of the current respiratory rate or calculate respiratory rate data representing the current respiratory rate based on the pre-processed data from step 702. Determining the respiratory rate at step 704 may be carried out before, in parallel, or after step 703. The respiratory rate data can be received from other sources or sensors, or alternatively may be calculated from the flow parameter data or flow parameter variation data.

The algorithm may calculate one or more additional breathing parameters or ratios based on the breathing parameter ratio representing $\frac{T_i}{T_{tot}}$ and the respiratory rate data. Such additional breathing parameters or ratios may include, for example, inspiration time (T_i), expiration time (T_e), total respiration time (T_{tot}), ratio of inspiration time to expiration time (the I:E ratio, $\frac{T_i}{T_e}$), ratio of expiration time to inspiration time ($\frac{T_e}{T_i}$), and/or ratio of expiration time to total respiration time ($\frac{T_e}{T_{tot}}$).

As will be appreciated, as new flow rate data arrives and is processed by the algorithm, the algorithm continues to update the breathing parameters being calculated, such that the parameters and/or ratios are updated in real-time (or close to real-time) as the respiratory apparatus is in operation and delivering high flow therapy.

At step 705, the algorithm 700 may optionally determine one or more additional breathing parameters and/or ratios based on the calculated breathing parameter ratio from step 703 and the respiratory rate data from step 704.

As new flow rate data arrives, the algorithm continues to execute and update the additional breathing parameters being calculated, such that the parameters and/or ratios are updated in real-time as the respiratory apparatus is in operation and delivering high flow therapy.

At step 706, the algorithm 700 may execute one or more actions and/or functions based on the calculated or updated primary breathing parameter ratio from step 703 and/or additional breathing parameters from step 705. By way of example only, the breathing parameter data generated by the algorithm during operation of the respiratory apparatus may be continuously fed to other control functions of the apparatus for the purpose of analysis, monitoring, display, alarms, storage, and/or notifications.

2.3 Example of off-therapy respiratory parameter estimation processes

With reference to Figures 7 to 10, examples of various methods for determining or estimating an off-therapy respiratory parameter of a patient will be described below, although it will be appreciated that alternative methods may be used. The methods and processes of estimating an off-therapy respiratory parameter of a patient will be described in the context of the example respiratory apparatus 100 described above, which is configured or operable to provide nasal high flow therapy via an unsealed patient interface. As explained earlier, the methods and processes may also be applied to other respiratory apparatus and/or to other modes of operation and/or modes of therapy delivered by such apparatus.

The example processes 2400, 2500 described may be performed once over a therapy session, or a sleep session that occurs during at least a segment of the therapy session. In other examples, they may be performed two or more times over a therapy session, or a sleep session that occurs during the therapy session.

In Figures 7 and 8, examples of a method 2400 of estimating an off-therapy respiratory parameter of a patient using a respiratory apparatus are shown. In these examples, the respiratory apparatus is configured to provide a flow of gases to a user, and comprises at least

a flow generator, one or more sensors, and a controller. The flow generator is configured to generate a flow of gases for the user at a plurality of flow rates, the plurality of flow rates comprising at least an operating flow rate and one or more intermediate flow rates. The one or more sensors are each configured to generate flow parameter data indicative or representative of one or more properties of the flow of gases.

The example process as shown in Figure 7 will now be described. The method 2400 may be executed or implemented by the controller of the example respiratory apparatus 100 described above. At step 2402, the controller performs the step of controlling the flow generator to generate or provide a flow of gases to a user or patient at an operating flow rate. The operating flow rate may be a therapeutic flow rate. The therapeutic flow rate may be suitable for providing high flow therapy to the patient.

At step 2404, the flow generator is controlled to provide a flow of gases at an intermediate flow rate. At step 2406, the controller is configured to receive flow parameter data while the patient is being provided with a flow of gases at the intermediate flow rate. The flow parameter data may be received from the one or more sensors. At step 2408, the controller is configured to estimate or determine a respiratory parameter of the patient while the patient is being provided with a flow of gases at the intermediate flow rate based at least on the received flow parameter data. At step 2410, the controller determines whether to further adjust the flow rate to a different/distinct intermediate flow rate. For example, the controller may determine that further adjustment in flow rate to a lower intermediate flow rate or a higher intermediate flow rate is required. If the controller determines a further intermediate flow rate is required, then the process returns to step 2404 to provide the flow of gases at a further intermediate flow rate, before performing steps 2406 to 2410 again. If the controller determines a further intermediate flow rate is not required, the process performs step 2412 and estimates an off-therapy respiratory parameter of the patient based at least on the estimated or determined respiratory parameters at each of the intermediate flow rates.

At step 2402, the controller performs the step of generating or providing a flow of gases to a user or patient at an operating flow rate. The operating flow rate may be a therapeutic flow

rate. The operating flow rate may be suitable for providing a high flow respiratory therapy to a patient. The operating flow rate may be configured or prescribed by a clinician.

At step 2404, the flow generator is controlled to provide a flow of gases at an intermediate flow rate. In some examples, one or more of the intermediate flow rates may comprise sub-therapeutic flow rates. In such examples, one or more of the intermediate flow rates may be lower than the operating flow rate.

In some examples, one or more of the intermediate flow rates may be therapeutic flow rates, or be therapeutically effective flow rates, wherein the one or more of the intermediate flow rates may be lower or slightly lower than the operating flow rate but still sufficiently high so as to provide at least some of the benefits of high flow therapy. In such examples, the intermediate flow rates may be less than the operating flow rate. The one or more intermediate flow rates, whilst still being therapeutic or therapeutically effective, will also have an effect on the breathing parameter when compared to the operating flow rate. For example, the respiratory rate of the patient may increase closer to the off-therapy level at the one or more intermediate flow rates when compared to the respiratory rate at the operating flow rate.

In some examples, the process 2400 may perform steps 2404 to 2410 two or more times, such that flow is provided at a plurality of intermediate flow rates. Step 2402 therefore may comprise, at one or more further intervals, adjusting the operating flow rate to a plurality of distinct intermediate flow rates.

In these examples, the step 2408 of estimating or determining a respiratory parameter of the patient based at least on the data received occurs at each intermediate flow rate, and is based on the flow parameter data received at said intermediate flow rate at step 2406.

In some examples, the intermediate flow rate at each progressive interval is lower than the intermediate flow rate at the previous interval. The flow rate may thus be reduced at each interval to a lower intermediate flow rate. The controller may gradually decrease the flow rate through a number of intermediate flow rates lower than the previous, performing steps 2406 to 2408 each at a reduced intermediate flow rate. Alternatively, the intermediate flow rates may

vary, for example, such that the plurality of intermediate flow rates alternate between two or more flow rates (that are nonetheless lower than the operating flow rate).

The controller may store a minimum or 'floor' flow rate. In some examples, the minimum flow rate may be a fixed value such that it applies to all patients who might use the respiratory therapy apparatus. In other examples, the minimum flow rate is a variable value which may change based on different therapy sessions and/or different patients. In these examples, the minimum flow rate may be dependent or based on at least the operating flow rate or prescribed therapeutic flow rate for the therapy session or patient. The minimum flow rate will be a flow rate that is not sufficiently low so as to present a risk to patients needing respiratory support, or at least not so low that the reduced flow rate would be noticeable to a patient (especially sleeping or resting patients).

At step 2410, the controller may compare the present intermediate flow rate to the minimum flow rate. The controller may determine whether the minimum flow rate has been reached. If the minimum flow rate has been reached, the controller may proceed to increase the flow rate back to the operating flow rate. The controller may gradually increase the flow rate back to the operating flow rate. The gradual increasing may involve increasing the flow rate to progressively higher intermediate flow rates that may each correspond to one or more of the intermediate flow rates previously used in the process. In other examples, the controller may increase the flow rate back to the operating flow rate in a ramping style, which may involve linearly (e.g., in a straight line) or nonlinearly (e.g., using a curve, exponential curve, or logarithmic curve) increasing the flow rate back to the operating flow rate, rather than implementing incremental increases. In some examples, the controller may step the flow rate back to the operating flow rate more rapidly or more slowly.

In other examples, the intermediate flow rate may be greater than or lower than the previous intermediate flow rate. As will be discussed later, the controller may gradually decrease the flow rate through a number of intermediate flow rates lower than the previous, performing steps 2406 to 2408 at each reducing intermediate flow rate. The controller may then determine that a minimum flow rate has been reached, after which the controller may gradually increase the flow rate through a number of intermediate flow rates greater than the previous,

performing steps 2406 to 2408 at each intermediate flow rate. The gradually increasing of the intermediate flow rates may involve increasing the flow rate to progressively higher intermediate flow rates that may each correspond to one or more of the intermediate flow rates previously used in the process, or, to flow rates which may be distinct intermediate flow rates from the intermediate flow rates previously used in the process.

In some examples, the flow rate is ramped gradually from the operating flow rate to each intermediate flow rate. Further, the flow rate may be ramped gradually from each intermediate flow rate to the next intermediate flow rate. In other examples, the flow rate is stepped between the operating and intermediate flow rates.

In some examples, the flow rate is maintained for a minimum or predetermined period of time at each of the one or more intermediate flow rates before steps 2406 and 2408 are performed. This allows the patient's respiratory parameter(s) to stabilise at that intermediate flow rate, which can result in more accurate determination or estimation of the respiratory parameter(s). The period of time before performing steps 2406 to 2408 may be at least long enough to enable residual effects of the therapy at the previous flow rate on the respiratory parameter of the patient to decay.

As such, the step of estimating or determining a respiratory parameter of the patient at each of the plurality of intermediate flow rates may occur a period of time after the flow rate has been changed to an intermediate flow rate. In some examples, the period of time may be pre-set or predetermined. The period of time may be a constant value throughout the process 2400. In other examples, the period of time may be variable between intervals. In such examples, the period of time may be related to the flow parameter data received. The period of time may be proportional to or have a fixed ratio with the flow parameter data or estimated respiratory parameter of the patient. Alternatively, the period of time may be inversely proportional to at least an estimated respiratory parameter of the patient.

For example, if the patient's respiratory rate is relatively high, then more respiratory cycles will be captured in a certain period of time. But if the patient's respiratory rate is relatively low, then fewer cycles will be captured in that certain period of time. If the aim is to capture a fixed number of respiratory cycles, then the time spent at each flow rate can be reduced/increased dependent on the measured/estimated respiratory rate of the patient.

Similar logic might also apply in example configurations where the respiratory parameter of the patient is their I:E ratio, as a higher respiratory rate usually means a shorter expiratory period and vice-versa — consequently, the patient's I:E ratio is likely to be higher if their respiratory rate is higher, and vice versa. However, I:E ratios may vary considerably at a particular respiratory rate, depending on various factors (including the patient's condition and physiology, whether they are awake or not, their stage of sleep — if sleeping— and transient breathing changes). Therefore, in such example configurations, the controller may be configured to identify particular uneven I:E ratios (e.g., breath cycles with significantly long expiratory periods versus inspiratory periods and therefore longer overall) and on this basis extend or shorten the period of time spent at a flow rate as appropriate.

At step 2406, the controller is configured to receive flow parameter data while the patient is being provided with a flow of gases at the intermediate flow rate. The flow parameter data may comprise flow rate data indicative or representative of the flow rate of the flow of gases provided by the flow generator. As discussed above, the example respiratory therapy apparatus 100 may comprise a flow rate sensor or sensors that are configured to sense and generate the flow rate data. The flow rate sensor or sensors may be positioned or located in or within a flow path of the flow of gases. More specifically, the flow rate sensor or sensors may be positioned or located at or near an outlet of a blower of the flow generator. The flow rate sensor or sensors may be in electrical communication with the controller.

Additionally, or alternatively, the flow parameter data may comprise pressure data indicative or representative of the pressure of the flow of gases at an outlet of the blower of the flow generator. As discussed above, the example respiratory therapy apparatus 100 may comprise a pressure sensor or sensors that are configured to sense and generate the pressure data. The pressure sensor or sensors may be positioned or located in or within a flow path of the flow of gases. More specifically, the pressure sensor or sensors may be positioned or located at or near an outlet of a blower of the flow generator. The pressure sensor or sensors may be in electrical communication with the controller.

At step 2408, the controller is configured to estimate or determine a respiratory parameter of the patient at the intermediate flow rate based at least on the received flow parameter data.

The step of estimating or determining the respiratory parameter of the patient at each of the plurality of intermediate flow rates may comprise assessing or processing the received flow parameter data. For example, this step may comprise assessing or processing the flow rate data and/or pressure data received at the intermediate flow rate to determine the respiratory parameter of the patient at said intermediate flow rate.

As described above, in some examples, the respiratory parameter of the patient may be the respiratory rate of the patient. Additionally, or alternatively, the respiratory parameter of the patient may be the inspiratory-expiratory time ratio of the patient.

For any one or more of these example respiratory parameters, it will be appreciated that they may be determined or estimated using the methods as previously described.

At step 2410, the controller determines whether to continue to a further intermediate flow rate. As discussed above, the controller may gradually decrease the flow rate through a number of intermediate flow rates lower than the previous, performing steps 2406 to 2408 at each reducing intermediate flow rate. The controller may then determine at step 2410 whether to continue to a further lower flow rate. This determination may be based on comparing the present intermediate flow rate to one or more thresholds or values. The thresholds or values may define a range and/or a minimum value for the flow provided to the patient. The range or minimum value may be predefined. The range or minimum value may be set by a clinician. In other examples, the range or minimum value may be determined by the controller based on the estimated or determined respiratory parameter(s) of the patient. The range or minimum value may define or relate to a minimum flow rate.

At step 2410, the controller may assess the present intermediate flow rate against the range or minimum value. If the intermediate flow rate is within the range and/or the minimum value has not yet been reached, then the process returns to step 2404 to provide the flow of gases at a further intermediate flow rate, before performing steps 2406 to 2410 again.

If the present intermediate flow rate is close to or outside the range, or is close to or outside the minimum value, then the controller at step 2410 may determine that further intermediate

flow rates are not required. Based on this determination, the controller may determine not to proceed back to step 2404, but to instead proceed to step 2412.

If the controller determines a further intermediate flow rate is required, then the process returns to step 2404 to provide the flow of gases at a further intermediate flow rate, before performing steps 2406 to 2410 again.

If the controller determines a further intermediate flow rate is not required, the process performs step 2412 and estimates an off-therapy respiratory parameter of the patient based at least on the estimated or determined respiratory parameters at each of the one or more intermediate flow rates.

As will be appreciated, in all examples of the present disclosure, the off-therapy respiratory parameter(s) of the patient are estimated while the respiratory therapy system is supplying air to the airway of the user. In some examples, one or more of the off-therapy respiratory parameter(s) of the patient are estimated while the patient is using the respiratory therapy system for therapeutic purposes.

In some examples, the method further comprises the steps of receiving flow parameter data at the operating flow rate; and then estimating or determining a respiratory parameter of the patient at the operating flow rate based at least on that flow parameter data received at the operating flow rate.

In such examples, the step 2412 of the process 2400 of estimating an off-therapy respiratory parameter of the patient may be based at least on the estimated or determined respiratory parameters at each of the plurality of intermediate flow rates and at the operating flow rate.

In some examples, the flow parameter data may comprise oxygen concentration data indicative or representative of the concentration of oxygen in the flow of gases provided by the flow generator. For example, the flow parameter data may comprise data indicative or representative of the fraction of delivered oxygen (FdO_2), the oxygen fraction of the delivered gases flow output by the respiratory therapy apparatus 100. The example respiratory therapy

apparatus 100 may comprises an oxygen concentration sensor or sensors that are configured to sense and generate the oxygen concentration data. The oxygen concentration sensor or sensors may be positioned or located in or within a flow path of the flow of gases.

The step 2412 of estimating the off-therapy respiratory parameter(s) of the patient may be performed using a model. The model may be a part of a function or algorithm. The model may be based on or may receive as inputs the estimated or determined respiratory parameter(s) at each of the plurality of intermediate flow rates. The model may further be based on or may receive as inputs the estimated or determined respiratory parameter(s) at the operating flow rate.

The respiratory therapy device may further comprise a non-transitory computer-readable medium that is accessible or in data communication with the controller. The non-transitory computer-readable medium may comprise a non-volatile memory. The model(s) may be stored in the non-volatile memory. In some examples, for example those which use more complex models which may require significant processing power, such model(s) may be stored on remote devices or servers and the respiratory device could simply outsource the processing to these other processors by transmitting the various inputs to the remote devices or servers, which would perform the processing.

In some examples, the model is a linear model, or multiple linear models. The model(s) may be a generalised linear model or models, and comprise one or more equations. The generalised linear model(s) may comprise appropriate coefficients for determining or estimating a specific off-therapy value for a respiratory parameter such that different terms of the model(s) and/or equation(s) may be weighted appropriately for the specific respiratory parameter, as will be explained in relation to further examples such as that relating to the off-therapy respiratory rate. The model(s) could be used for estimating one or more off-therapy respiratory parameters.

The model(s) may be further based on or may receive as input the flow parameter data and the estimated or determined respiratory parameter(s) at each of the plurality of intermediate flow rates. The model may be further based on or may receive as input the flow parameter data received and the estimated or determined respiratory parameter(s) at the operating flow rate

and the flow parameter data received and the estimated or determined respiratory parameter(s) at each of the plurality of intermediate flow rates.

In such examples, the flow parameter data may include oxygen concentration data. The model(s) may be based on or may receive as input the oxygen concentration data received at each of the plurality of intermediate flow rates. The model(s) may further be based on or may receive as input the oxygen concentration data received at the operating flow rate.

The model(s) may comprise one or more coefficients. In examples, the coefficients define, or represent, or model a relationship between the estimated or determined respiratory parameter(s) and the received flow parameter data at each flow rate.

In some examples, one or more of the coefficients may be predetermined or pre-set. One or more of the coefficients may be based on collected patient data. In some examples, one or more of the coefficients may be generated using a supervised machine learning algorithm with collected patient data. The patient data may be collected from broad range of patients. The patient data should allow the coefficient(s) to be relatively universally applied across a general patient population. However, it is contemplated that different coefficients may be generated and used for different patient populations – for example, based on patients identified as having certain respiratory conditions and/or disease states. For example, there could be specific models for different types or groupings of patients. In such examples, the coefficients may differ between the models, based on the categorised types or groupings of patients. Examples of different patient groupings or types include: COPD Stages I-IV, bronchiectasis, acute heart failure, ARDS, pulmonary oedema, and pneumonia patients, to provide some examples.

The coefficients may be generated using a supervised machine learning algorithm(s) with collected patient data, wherein measured or determined respiratory parameter and flow rate data from at least one patient population may be supplied to the supervised machine learning algorithm(s). The machine learning process(es) may comprise inputting data relating to respiratory parameter(s) and corresponding flow parameter data measured or determined from one or more patients. The machine learning process(es) may comprise inputting data relating to respiratory parameter(s) and corresponding flow parameter data measured or

determined from multiple patient populations. Each patient population may correspond to a different population associated with a particular disease and/or disease state, as described above.

In some examples, the model(s) and/or the coefficient(s) which make up the model(s) may be generated by one or more machine learning algorithms. The machine learning algorithm(s) may be run or performed to train suitable models for use in estimating the off-therapy respiratory parameter(s). The model(s) may be used to determine the coefficients that providing weightings to the different terms in the model. The generated model(s) may be implemented on the respiratory therapy device such that the controller of the device is configured to estimate the off-therapy respiratory parameter of the patient using the generated model(s) as described. The controller of the respiratory therapy device may be programmed with the pre-generated model(s) and can take the relevant parameters/variables as inputs to the model(s) in order to process them.

The machine learning algorithm(s) may require significant processing resource and so may not be suitable to run on the controller of a respiratory therapy device which may have limited computational resource due to being an embedded system. As such, the machine learning algorithm(s) which may be used to generate the coefficient(s) may be performed on processors or servers remote to the respiratory therapy device. However, in some examples, if the resources are available on the controller of the respiratory therapy device, the machine learning algorithm(s) may be performed on the controller of the respiratory therapy device.

The model(s) can describe non-linear relationships between variables and outputs. These models may include Support Vector Machines (SVM), tree-based models such as but not limited to decision trees, Random Forest or XGBoost (eXtreme Gradient Boosting) algorithms, and/or artificial neural networks. The models may also include, among others, Generalized Linear Models, Linear or Logistic Regression and Linear Discriminant Analysis models. The models may include Auto-Regressive Integrated Moving Average models (ARIMA). Input features may comprise raw or pre-processed, normalized and/or combined data prior to being fed into these models (e.g., with dimensionality reduction methods such as, for example, Principal Component Analysis, Multiple Component Analysis).

As well as coefficient(s), the model(s) for estimating the off-therapy respiratory parameter(s) of the patient may comprise one or more variables. The variables may include or be based on the estimated or determined respiratory parameter(s) and/or the flow parameter data at each flow rate.

In examples, the variables used in the model may comprise at least one or more of the following:

- an average of the estimated or determined respiratory parameter of the patient at each of the plurality of intermediate flow rates. For example, after running the function several times, a set of data would be gathered relating changes in the patient's respiratory parameter to changes in flow rate e.g., the change in the patient's respiratory parameter when flow changes, based on the average of the estimated or determined respiratory parameter of the patient at each of the plurality of intermediate flow rates. The model may then use this collected data to extrapolate an off-therapy respiratory parameter at 0 L/min. The effects of flow (and optionally, supplementary oxygen) and changes thereof on other respiratory parameters, such as the respiratory rate of the patient, may be modelled similarly.
- a difference between the operating flow rate and a/the minimum flow rate. This minimum flow rate may be zero, or a non-zero value that is expected to result in no (or very minimal) reduction of the respiratory parameter (i.e., it has little or no therapeutic effect). This minimum flow rate may be a fixed 'target' which is dependent on the baseline/operating flow rate. The respiratory therapy device may not ever actually drop to this flow rate.
- a difference between the respiratory parameter of the patient at the operating flow rate and an average of the estimated or determined respiratory parameter of the patient at each of the plurality of intermediate flow rates, wherein the difference is divided by a difference between the operating flow rate and the one or more intermediate flow rates.
- a difference between the oxygen concentration data of the flow of gases (i.e., the fraction of delivered oxygen, FdO_2 , or the fraction of inspired oxygen, FiO_2) at one or more intermediate flow rates and a reading of the ambient oxygen concentration level.

In one example, the model(s) may be used at each intermediate flow rate point. The model(s) may generate multiple values relating to a change in the patient's respiratory parameter(s) given a change in flow rate, and use these multiple values together to project or calculate a trajectory of the patient's respiratory parameter as it changes with further reductions in flow rate. The model(s) may use temporal relationship data between sets and/or multiple sets of measurements for a patient to estimate the patient's off-therapy respiratory parameter. In other words, in some examples, the data input to the model(s) may include data indicating a series of data points are from sequential time-points — e.g., each input may be a vector or matrix containing a plurality of data points across different sequential time-points.

In another example, the model(s) may be run at one intermediate flow rate point and use the change in the patient's respiratory parameter(s) given the change in flow rate value to make an estimate of the patient's off-therapy respiratory parameter.

The model(s) is/are configured to output a value corresponding to an estimation of one or more off-therapy respiratory parameters of the patient. In other words, an estimation of what one or more respiratory parameters of the patient would be when the respiratory therapy apparatus is providing no flow.

In some examples, the model(s) is/are configured to output a change in the patient's respiratory parameter(s) given a change in flow rate. If the change in flow corresponds to a drop to zero flow (i.e., no therapy), then this could be used to determine the off-therapy respiratory parameter.

In some examples, the model(s) may be configured to output a value relating an expected change in the respiratory parameter of the patient to a change in flow rate. The model(s) may provide an output that quantifies the expected change in the respiratory parameter(s) due to changing the flow rate from the operating flow rate to a sub-therapeutic flow rate(s), wherein the sub-therapeutic flow rate is an intermediate flow rate that is low enough to be considered to provide a diminished therapeutic effect. The relationship may allow extrapolation of the respiratory parameter(s) at intermediate flow rates to below the minimum flow rate, without

requiring the flow rate to be reduced significantly, such that the sleeping or resting patient or therapy would be disrupted.

In some examples, the controller may further be able to identify whether the measured or determined patient-specific data is being accurately matched by the model(s). This may occur over several therapy sessions. For example, the estimated or determined patient parameter(s) and/or the changes in the estimated or determined patient parameter(s) in response to changes in flow rate could be compared with a predicted or estimated respiratory parameter that the model outputs. If there is a consistent discrepancy, the algorithm may perform a recalibration of the coefficients or identify a more suitable set of coefficients for the patient. For example, the controller may not have knowledge of an updated disease state of the patient, if they have transitioned from COPD Stage I to II, following an exacerbation. The controller (or an external/remote computing device that receives data from the respiratory therapy device) may nonetheless be able to determine whether the patient's response to changes in flow is better aligned with a different model. For example, it might determine that the patient's state better corresponds to a COPD Stage II patient, rather than Stage I, and thus switch to a model relating to a Stage II patient.

In some examples, the estimated or determined respiratory parameter(s) at the intermediate flow rates may be extrapolated using a model(s) to estimate the off-therapy respiratory parameter(s). The extrapolation may be performed using the same model as described above, or another appropriate technique.

In some examples, the model comprises a fitted linear equation or fitted linear model. The fitted linear equation or fitted linear model is performed using data comprising estimates of a respiratory parameter of the patient at each intermediate flow rate, and measurements of said intermediate flow rates. The model may extrapolate the estimated or determined respiratory parameter(s) at the intermediate flow rates based on the time-series data. Standard techniques such as quadratic interpolation or application of ARIMA (auto-regressive integrated moving average) models could be used.

In some examples, the estimate of the off-therapy respiratory parameter(s) may be determined via inference, using a combination (e.g., an average or weighted average) of multiple values of the estimated or determined respiratory parameter(s) at the intermediate flow rates computed during the process 2400.

The model may comprise a fitted equation that can be used to extrapolate an off-therapy value of the respiratory parameter of the patient based at least on the estimated or determined respiratory parameter at each of the plurality of intermediate flow rates. The fitted equation is configured to provide an extrapolated respiratory parameter of the patient based at least on the estimated or determined respiratory parameter determined at each of the plurality of intermediate flow rates.

The model could be run several times, for example, the respiratory parameter at the operating flow rate could be determined or estimated, and then ramp the flow to one or more intermediate flow rates, wherein the respiratory parameter at each intermediate flow rate is determined or estimated, which can enable a good estimate of the off-therapy respiratory rate to be extrapolated. By taking several estimates or determinations of the respiratory parameter of the patient at different flow rates and determining several values representing the change in respiratory parameter compared to change in flow rate from the model, the trajectory of the respiratory parameter as it approaches an off-therapy flow rate can be determined.

In some examples, the process 2400 may proceed to adjust the flow rate provided to sub-therapeutic flow rates, which are below the minimum flow rate, after stepping through a plurality of intermediate flow rates. In situations where the prescribed operating flow rate of the apparatus is already comparatively low (e.g., at or below 35 L/min compared to the 60 L/min or even 70 L/min upper end of flow rates typically used in high flow therapy), the controller may proceed to adjust the flow rate provided to these sub-therapeutic flow rates. It is possible to adjust to sub-therapeutic flow rates without disrupting the patient because the flow rates may still be on the lower end of typical high flow therapy flow rates. Reducing the flow rate being provided to the patient from 60 to 10 L/min is a large decrease, and will likely be noticeable to the patient, perhaps enough to awaken or alert the patient. In comparison, dropping from 30 to 25 L/min is a smaller change that might not awaken or alert the patient.

The changes between the intermediate flow rates needed to observe changes in the patient's respiratory parameters in the present disclosure may be fairly small, and may be on the order of anywhere between (and including) 1 L/min to 10 L/min. In examples, a 10% reduction in flow rate between flow rates (i.e., a drop of flow rate from a 30 L/min therapeutic flow rate to a reduced flow rate of 27 L/min for example) might be sufficient to have a noticeable effect on the received readings while avoiding disruption to the patient.

In this example, a value close to or substantially corresponding to the off-therapy respiratory parameter(s) of the patient can be measured or determined, rather than modelled or extrapolated as previously described. In these examples, the off-therapy respiratory parameter(s) of the patient may be measured or determined using the method described in relation to step 2408 of the process 2400.

The advantage of this approach is that there may be less extrapolation required as compared with the previous approach of using a model, or extrapolating the data. This approach may involve dropping the flow rates to lower sub-therapeutic levels (although not all the way to zero or non-therapeutic levels), such that less extrapolation of the data is required. The data collected at these lower sub-therapeutic flow rates may be closer to the data that would be collected when therapy is not being provided, and so the estimation of the off-therapy respiratory parameter may thus occur at a lower flow rate value as compared to the previous approach. For example, since a respiratory parameter measured at 20 L/min is typically closer to that which would be measured at (or close to) 0 L/min, than if the parameter was measured at 40 L/min the respiratory parameter estimated at the lower sub-therapeutic flow rate (20 L/min) will be closer to that which would be measured at zero flow rate.

In some examples, time series data of the estimated or determined respiratory parameter(s) of the patient at the sub-therapeutic flow rate(s), which are below the minimum flow rate, and the estimated or determined respiratory parameter(s) of the patient at the plurality of intermediate flow rates can be inputted to an equation or model and used to estimate the respiratory parameter(s) of the patient as the flow rate tends to zero, i.e., the off-therapy respiratory parameter(s). In some examples, the model may be a fitted model as previously described which extrapolates the values.

In some examples, the model may comprise a fitted equation that can be used to extrapolate off-therapy values of the respiratory parameter of the patient based at least on the estimated or determined respiratory parameter at each of the plurality of intermediate flow rates. The fitted equation may be configured to provide an extrapolated respiratory parameter of the patient based at least on the estimated or determined respiratory parameter at each of the plurality of intermediate flow rates. The extrapolated respiratory parameter of the patient may be an approximation of the respiratory parameter of the patient at a flow rate below at least the lowest intermediate flow rate.

In some of these examples, the period of time spent at the sub-therapeutic flow rate(s) before receiving flow parameter data (step 2406) and then estimating or determining the respiratory parameter(s) of the patient (step 2408), which are below the minimum flow rate, should be long enough to reduce any residual impact of prior flow rates provided on the patient's respiratory parameter(s). Additionally, or alternatively, the period of time spent before receiving flow parameter data (step 2406) and then estimating or determining the respiratory parameter(s) of the patient (step 2408) may be inversely proportional to a previously estimated respiratory parameter(s), as noted previously, so as to ensure a sufficient number of respiratory cycles are included in the data for processing.

Other additional features

The example process shown in Figure 8 will now be described. The example process shown in Figure 8 corresponds to the process shown in Figure 7, however it shows additional steps which may be performed. Steps 2402, 2404, 2406, 2408, 2410, and 2412 are common to both the examples shown in Figure 7 and Figure 8, and it will be appreciated they are performed as described in relation to Figure 7 above. Steps 2403, 2405, 2407, and 2409 are additional steps only of the example shown Figure 8. These additional steps will now be described.

At step 2403 the controller is configured to receive flow parameter data at the operating flow rate. As will be appreciated, the features of this step 2403 correspond to those of step 2406 as

previously described. The difference being that the flow parameter data at step 2403 is received at the operating flow rate.

In some examples, the controller is configured to receive flow parameter data at step 2403 after a minimum time period has elapsed from the start of a therapy session. The pre-determined time period may be at least long enough to enable the breathing of the patient to sufficiently stabilise.

At step 2405 the controller may be configured to assess whether one or more breathing stability criteria are being met. This step may comprise determining a status of the patient's respiratory parameter based on the flow parameter data received at step 2403.

In most configurations, it is optimal for the patient to have a stable respiratory parameter before performing the steps of the process described. If the patient's breathing is not stable, then variations in the respiratory parameter(s) that is/are estimated or determined in the process of adjusting to intermediate flow rates could be incorrectly associated with the change(s) in flow rate.

Additionally, a stable respiratory rate in particular might be used to determine if the patient is asleep or approaching sleep. Performing the flow reduction and measurement process of the present implementation while the patient is asleep may be preferable as the patient is less likely to vary their respiratory parameters (in response to variables aside from the therapy device flow rate). It is not necessary for the patient to be asleep however – provided the patient's breathing is sufficiently stable, the process described can be carried out as intended.

As such, at step 2405 the controller may be configured to assess whether one or more breathing stability criteria are being met. If the controller determines that the breathing stability criteria are met, then the method 2400 progresses to step 2404 and controls the flow generator to provide the flow of gases at the plurality of intermediate flow rates.

The controller may determine that the breathing stability criteria are met based on the status of the patient's respiratory parameter indicating that the patient's respiratory parameter is substantially stable.

In some examples, the step of determining the status of the patient's respiratory parameter may comprise determining an indication or estimate of the respiratory parameter of the patient. The indication or estimate of the respiratory parameter of the patient may be based on flow parameter data received at one or more intervals while at the operating flow rate. The step of determining the status of the patient's respiratory parameter may additionally, or alternatively comprise determining an indication or estimate of the respiratory parameter of the patient using data received from one or more sensors configured to measure a patient parameter. The data from the sensor(s) received at one or more intervals while at the operating flow rate. For example, the sensor may comprise any one or more of: a connected pulse oximeter, a heart rate sensor, and/or an external respiratory rate sensor. The sensor(s) may be connected to the controller of the respiratory therapy apparatus via a wired or wireless connection.

The indication or estimate of the respiratory parameter of the patient at each interval may be compared to at least the indication or estimate of the respiratory parameter of the patient at one or more previous intervals.

In such examples, the status of the patient's respiratory rate relates to a degree or amount of change between the indication or estimate of the respiratory parameter of the patient determined at a present interval to the indication or estimate of the respiratory parameter of the patient determined at one or more previous intervals, based on said comparison.

The controller may determine, for example, that the status of the patient's respiratory rate indicates that the respiratory rate of the patient is either: increasing, or decreasing, or substantially stable, based on said comparison.

Based on the controller determining that the status of the patient's respiratory parameter (e.g., respiratory rate) indicates that the respiratory parameter of the patient is substantially stable,

the controller may determine that the breathing stability criteria are met, and the process may proceed to step 2404.

In some examples, the step 2405 of determining the status of the patient's respiratory parameter further comprises comparing the status of the patient's respiratory parameter to one or more thresholds.

In further examples, the determination of the status of the patient's respiratory parameter comprises assessing a specific patient breathing stability criteria. Assessing a patient breathing stability criteria may comprise comparing a measured or determined patient respiratory parameter or a breathing stability parameter to one or more thresholds. The measured or determined patient respiratory parameter or a breathing stability parameter may be a measure of the variability of one or more respiratory parameters (such as the respiratory rate) of the patient. The measure of the variability of the or each respiratory parameter may be a ratio of standard deviation of the respiratory parameter and an average of the respiratory parameter over two or more measured intervals.

In some examples, the measure of the variability of the or each respiratory parameter may be a coefficient of variability. In some examples, the measure of the variability of the respiratory rate may be a ratio of standard deviation of a signal envelope of the respiratory parameter and an average of the signal envelope of the respiratory parameter.

Waiting for an interval

At step 2407, the controller 2400 proceeds to wait for an interval or time period after adjusting the flow rate to an intermediate flow rate. At this step, the controller may maintain the flow rate for a minimum period of time at each of the one or more intermediate flow rates before steps 2406 and 2408 are performed. This allows the patient's respiratory parameter(s) to stabilise at that intermediate flow rate, which can result in more accurate determination or estimation of the respiratory parameter(s). The period of time before performing steps 2406 to 2408 may be at least long enough to enable residual effects of the previous flow rate on the respiratory parameter of the patient to decay.

As such, the step 2406 of estimating or determining a respiratory parameter of the patient at each of the plurality of intermediate flow rates may occur a period of time after the flow rate has been changed to an intermediate flow rate. In some examples, the period of time may be preset or predetermined. The period of time may be a constant value throughout the process 2400. In other examples, the period of time may be variable between intervals. In such examples, the period of time may be related to the flow parameter data received. The period of time may be proportional to or have a fixed ratio with the flow parameter data or estimated respiratory parameter of the patient. Alternatively, the period of time may be inversely proportional to at least an estimated respiratory parameter of the patient.

For example, if the patient's respiratory rate is relatively high, then more respiratory cycles will be captured in a certain period of time. But if the patient's respiratory rate is relatively low, then fewer cycles will be captured in that certain period of time. If the aim is to capture a fixed number of respiratory cycles, then the time spent at each flow rate can be reduced/increased dependent on the measured/estimated respiratory rate of the patient.

Similar logic might also apply in example configurations where the respiratory parameter of the patient is their I:E ratio. Provision of high flow therapy may result in a lengthened expiratory phase of the breathing cycle, where higher flow rates increase the expiratory phase duration. Thus, the I:E ratio will decrease as flow increases. The respiratory rate may also be decreasing in parallel. Conversely, when flow is decreased, the expiratory phase will decrease (while the respiratory rate may also be increasing in parallel); consequently, the I:E ratio will increase in this scenario. The patient's I:E ratio is likely to be higher if their respiratory rate is higher, and vice versa, but this may not always be the case. An increasing I:E ratio means increasing towards 1:1 (which indicates severe hyperventilation), while a decreasing I:E ratio means decreasing towards 1:2–1:3 (healthy levels).

Returning to operating flow rate

After step 2412 has been performed, and the controller has determined a value of the estimate for the off-therapy respiratory parameter(s) of the patient, the method 2400 may further comprise returning the flow rate to the operating flow rate. The controller may return to the operating flow rate at step 2409. The operating flow rate may be considered the initial flow rate.

In some examples, step 2409 may occur by increasing the operating flow rate to one or more increasing intermediate flow rates. The controller may gradually increase the flow rate at a number of intermediate flow rates greater than the previous. The gradual increases may correspond to one or more of the intermediate flow rates previously used in the process or one or more new or different intermediate flow rates. In other examples, the controller may increase the flow rate back to the operating flow rate in a ramping style (e.g. in a linear or nonlinear manner such as that previously described), or may step the flow rate back to the operating flow rate more rapidly or more slowly.

In other examples, the intermediate flow rate may be greater than or lower than the previous intermediate flow rate. As will be discussed later, the controller may gradually decrease the flow rate through a number of intermediate flow rates lower than the previous, performing steps 2406 to 2408 at each reducing intermediate flow rate.

As previously discussed, the controller may store a minimum flow rate. The controller may determine that a minimum flow rate has been reached at step 2410, after which the controller may gradually increase the flow rate back towards the operating flow rate at step 2409. The increase towards the flow rate to the operating flow rate at step 2409 may be through a number of intermediate flow rates greater than the previous. In some examples, the controller may also perform steps 2406 to 2408 at each increasing intermediate flow rate. The increasing intermediate flow rates may correspond to one or more of the intermediate flow rates previously used in the process, or may be distinct or new intermediate flow rates.

In some examples, after step 2412 has been performed, and the controller has determined a value of the estimate for the off-therapy respiratory parameter(s) of the patient using any of the above-described methods, the value of the estimated off-therapy respiratory parameter(s) of the patient may be outputted by the controller or used by the controller.

2.4 Example of off-therapy respiratory rate estimation processes

As shown in Figures 9 and 10, a method 2600 of estimating an off-therapy respiratory rate of a patient using a respiratory apparatus is shown. The steps of the method 2600 described are similar to the method 2400 described previously, however they relate to examples where the

off-therapy respiratory rate of the patient is estimated, the off-therapy respiratory rate being a specific type of off-therapy respiratory parameter.

It will be appreciated that steps described in relation to 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, and 2412 of method 2400 in Figure 7 and Figure 8 correspond to the steps 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, and 2612 of method 2600 shown in Figure 9 and Figure 10. It will be appreciated the steps of method 2600 differ from those of step 2400 in that they specifically relate to determining the off-therapy respiratory rate of the patient.

The method 2600 shown in Figures 9 and 10 of estimating an off-therapy respiratory rate of a patient will now be described.

At step 2602, the controller performs the step of generating or providing a flow of gases to a user or patient at an operating flow rate. The operating flow rate may be a therapeutic flow rate. The therapeutic flow rate may be suitable for providing high flow therapy to the patient.

At step 2604, the flow generator is controlled to provide a flow of gases at an intermediate flow rate. At step 2406, the controller is configured to receive flow parameter data while the patient is being provided with a flow of gases at the intermediate flow rate. The flow parameter data may be received from the one or more sensors.

At step 2608, the controller is configured to estimate or determine a respiratory rate of the patient while the patient is being provided with a flow of gases at the intermediate flow rate based at least on the received flow parameter data.

At step 2610, the controller determines whether to further adjust the flow rate to another intermediate flow rate. For example, the controller may determine that further adjustment in flow rate to a lower intermediate flow rate or a higher intermediate flow rate is required. If the controller determines a further intermediate flow rate is required, then the process returns to step 2604 to provide the flow of gases at a further intermediate flow rate, before performing steps 2606 to 2610 again.

If the controller determines a further intermediate flow rate is not required, the process performs step 2612 and estimates the off-therapy respiratory rate of the patient based at least on the estimated or determined respiratory rate at each of the intermediate flow rates.

The subtleties between methods 2612 and 2412 relating specifically to the off-therapy respiratory rate of the patient being estimated will now be described.

As with the step 2412 previously described, step 2612 of estimating the off-therapy respiratory rate of the patient may be performed based on or may receive as inputs the estimated or determined respiratory rate from step 2608 at each of the plurality of intermediate flow rates.

The off-therapy respiratory rate of the patient may be determined using a model. The model may be a part of a function or algorithm. The model may be based on or may receive as inputs the estimated or determined respiratory rate at each of the plurality of intermediate flow rates. The model may further be based on or may receive as inputs the estimated or determined respiratory rate at the operating flow rate.

In some examples, the model is a linear model or models. The model(s) may be a generalised linear model or models and can comprise one or more equations. The generalised linear model(s) may comprise appropriate coefficients for determining or estimating a specific off-therapy value for the respiratory rate.

The model(s) may be further based on or may receive as input the flow parameter data and the estimated or determined respiratory rate at each of the plurality of intermediate flow rates. The model may be further based on or may receive as input the flow parameter data received and the estimated or determined respiratory rate at the operating flow rate and the flow parameter data received and the estimated or determined respiratory rate at each of the plurality of intermediate flow rates.

The model(s) for estimating the off-therapy respiratory rate of the patient ($RR_{off-therapy}$) may comprise one or more variables. The variables may include or be based on the estimated or determined respiratory parameter(s) and/or the flow parameter data at each flow rate.

For example, the model for estimating the off-therapy respiratory rate of the patient may take into account each of the estimated or determined respiratory rates of the patient ($RR_{intermediate}$) that are computed when at each of the intermediate flow rates ($Q_{intermediate}$).

Additionally, the parameters used in the model may comprise at least one or more of the following:

- an average (mean) of the determined or estimated respiratory rate of the patient at the operating flow rate ($\mu_{RR_{operating}}$),
- an average of the estimated or determined respiratory rate of the patient at each of the plurality of intermediate flow rates ($\mu_{RR_{intermediate}}$),
- a difference between the operating flow rate ($Q_{operating}$) and the minimum flow rate ($Q_{minimum}$), the difference being ($Q_{operating} - Q_{minimum}$).
- a difference between the estimated or determined respiratory rate of the patient at the operating flow rate ($RR_{operating}$) and an average of the estimated or determined respiratory rate of the patient at each of the plurality of intermediate flow rates ($RR_{intermediate}$), wherein the difference is divided by a difference between the operating flow rate and the one or more intermediate flow rates i.e.,

$$\left[\frac{(\mu_{RR_{operating}} - RR_{intermediate})}{(Q_{operating} - Q_{intermediate})} \right];$$

The linear model may also consist of a series of coefficients (α_n) which may weight each of the above terms of the models by their effect on the estimate of the change in flow. The coefficients may define a relationship between the estimated or determined respiratory parameter(s) and the received flow parameter data at each flow rate, as previously described.

In an example, the model for estimating the off-therapy respiratory rate of the patient may take a form such as follows:

$$RR_{off-therapy} = \alpha_1 \mu_{RR_{operating}} + \alpha_2 (Q_{operating} - Q_{minimum}) + \alpha_3 \left[\frac{(\mu_{RR_{operating}} - RR_{intermediate})}{(Q_{operating} - Q_{intermediate})} \right]$$

In further examples, the model for estimating the off-therapy respiratory rate of the patient may additionally comprise a parameter relating a difference between the oxygen concentration data of the flow of gases at one or more intermediate flow rates and an ambient reading of oxygen concentration level ($FiO_{2_{delivered}} - FiO_{2_{ambient}}$). In such examples, the model for estimating the off-therapy respiratory rate of the patient may take a form such as follows:

$$RR_{off-therapy} = \alpha_1 \mu_{RR_{operating}} + \alpha_2 (Q_{operating} - Q_{minimum}) + \alpha_3 \left[\frac{(\mu_{RR_{operating}} - RR_{intermediate})}{(Q_{operating} - Q_{intermediate})} \right] + \alpha_4 (FiO_{2_{delivered}} - FiO_{2_{ambient}})$$

In a further example, the model for estimating the off-therapy respiratory rate of the patient may output $\frac{\Delta RR}{\Delta Q}$, an estimated change in respiratory rate due to a change in flow, or more specifically, the change in the respiratory rate between $Q_{operating}$ and $Q_{intermediate}$, where the model may take a form such as follows:

$$\frac{\Delta RR}{\Delta Q} = \alpha_1 \mu_{RR_{operating}} + \alpha_2 (Q_{operating} - Q_{minimum}) + \alpha_3 \left[\frac{(\mu_{RR_{operating}} - RR_{intermediate})}{(Q_{operating} - Q_{intermediate})} \right]$$

It is important to note that the example above describes the implementation of a generalized linear model, but the same features could be used to train a more complex model as described above (Tree-Based Models, Support Vector Machines, Artificial Neural Networks, etc.). The data inputs may be pre-processed and/or combined through a dimensionality reduction algorithm (e.g., Principal Component Analysis), and/or combined with additional metadata (e.g., demographics data, data about a patient's condition, etc.).

Finally, model architectures may or may not consider the temporal relationship between different measurements for a given patient (e.g., implementing or not implementing a time series model).

2.5 Other aspects

a) Determining the difference between on and off therapy respiratory parameters (ΔRP)

In some examples, the method 2400/2600 may further comprise the step of determining a difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient (ΔRP).

The difference (ΔRP) between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient may be used as a therapy efficacy indicator. It can also double as a compliance or adherence indicator. For example, a low difference might suggest poor therapeutic relief, which may be a predictor that the patient may be less likely to comply with or adhere to a therapy prescription.

In some examples, the difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient (ΔRP) may be provided or outputted as a numeric value. For example, the difference may be provided or outputted as a value relating to the number of breaths per minute difference between the determined or estimated on-therapy and off-therapy respiratory parameters.

Alternatively, or additionally, the difference ΔRP may be provided or outputted as a percentage difference. For example, the difference may be provided or outputted as a percentage change in the respiratory parameter of the patient between the measured on-therapy value(s) and the estimated off-therapy value.

The determination of the difference ΔRP between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient is further based on one or more average values of off-therapy respiratory parameter of the patient determined over multiple therapy sessions and/or multiple flow cycles over one therapy session.

The controller may in some configurations perform multiple flow reduction and estimation cycles, (i.e., method 2400/2600) over the course of one or multiple therapy sessions. The data from the multiple cycles may be treated separately, or combined (e.g., averaged) for use in further processing and/or applications. By performing multiple cycles and computing averages, the controller may be able to successfully apply more subtle reductions in flow to estimate the off-therapy respiratory parameter(s) of the patient. Performing more subtle reductions in flow with minimal cycling may have a less obvious effect on the respiratory parameter(s) of the patient, which could diminish the accuracy of the off-therapy parameter estimation(s). This may be mitigated by running multiple cycles with more subtle flow rate reductions. It will be appreciated that for the flow rate reduction of the present disclosure, multiple cycles may be beneficial to the accuracy of the estimations or determinations.

The difference ΔRP , whether represented as a numerical value or percentage, may provide a good indicator of therapy efficacy. It may also be useful as an indicator of therapy adherence – especially if tracked over extended lengths of time (weeks, months, years). In part, this is because it is an objective descriptor of perceived therapeutic relief. It is an objective descriptor of perceived therapeutic relief as it can show how much of an effect the therapy is having on the respiratory parameters of the patient — in other words, how well the therapy is being received by the patient. If tracked over time, the ΔRP may show improvement in the respiratory parameter(s) of the patient over a long time period (improvement may mean a decrease or increase in the difference, depending on what the parameter observed), which could indicate adherence to a therapy prescription, as well as efficacy of the therapy.

The output from the ΔRP determination process could be used in a variety of clinician-informative applications. These could include recording ΔRP for each session and

transmitting the records to a clinician device or server, presenting alerts tied to ΔRP to the clinician, and/or displaying ΔRP as part of an adherence monitoring program.

b) Performing the above steps multiple times over a therapy session

In examples, the method 2400 (and 2600) can be repeated multiple times. Ideally, this is done as long as breathing remains stable e.g., if the patient's respiratory parameter or the coefficient of variability (as discussed previously in relation to the stability criteria) thereof starts to increase while a continuous operating flow rate is provided. It may be advantageous to gather multiple off-therapy estimates and average them, as this may help to flatten out any inconsistencies and reduce the impact of any spurious estimates that could occur (due to sensor readings that are excessively noisy, for example).

When multiple off-therapy respiratory parameter estimates are computed over one or multiple therapy sessions, the controller may use a vector (e.g., of N length) or another suitable data structure (e.g., a matrix, a list, etc.) that stores both the off-therapy respiratory parameter estimate(s) (RP_{subt}) and the value(s) of the average of the estimated or determined respiratory parameters at the operating flow rate(s) ($\mu_{RP_{baseline}}$).

The method may then comprise computing an estimate of the average change in the respiratory parameter (that being the change in the respiratory parameter from a baseline (such as at the operating flow rate), due to the reduction of flow rate to sub-therapeutic levels, wherein $\mu_{RP_{increase}}$:

$$\mu_{RP_{increase}} = \frac{\sum_1^n (RP_{subt}[i] - \mu_{RP_{baseline}}[i])}{\sum_1^n \mu_{RP_{baseline}}[i]} * 100$$

where $\mu_{RP_{increase}}$ is equivalent to the difference ΔRP between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient, RP_{subt} is a value of the estimated off-therapy respiratory parameter of the patient, and $\mu_{RP_{baseline}}$ is similarly the value of the average of the respiratory parameter of the patient at the operating flow rate. The summation may be performed over the range of indices 1 to N relating to different readings taken in time. In this example, $\mu_{RP_{increase}}$ is represented as a percentage, but other representations are possible. For example, $\mu_{RP_{increase}}$ could be computed as an absolute numerical value (i.e., in the units of the

respiratory parameter — breaths per minute if the respiratory parameter is respiratory rate) by omitting the multiplication element of the equation above.

Because the absolute values of the determined respiratory parameter for patients is dependent on a range of physiological factors, including the underlying respiratory conditions patients may have, it may not necessarily be useful to directly monitor (or perform other functions based on) the numerical values of the respiratory parameter themselves. Whereas studying the percentage deviation provides a more relative indicator of the responsiveness of a patient to high flow therapy, the specific therapy parameter configuration, and/or their adherence to a therapy programme.

c) Accounting for the effects of supplementary O₂ on the off-therapy RR estimate

In some examples, the flow parameter data comprises oxygen concentration data indicative or representative of the concentration of oxygen of the flow of gases provided by the flow generator. The apparatus may comprise an oxygen concentration sensor or sensors that are configured to sense and generate the oxygen concentration data. The oxygen concentration sensor or sensors may be positioned or located in or within a flow path of the flow of gases. Additionally, the apparatus may comprise an oxygen concentration sensor or sensors that are configured to sense and generate oxygen concentration data relating to the oxygen concentration of the ambient air around the apparatus, which may be taken in by the apparatus prior to addition of supplementary O₂.

In such examples, the step of estimating an off-therapy respiratory parameter of the patient may be further based on the oxygen concentration data received at each of the plurality of intermediate flow rates and/or the oxygen concentration data relating to the oxygen concentration of the ambient air.

In addition to the flow rate, the presence of supplemental oxygen in the breathing gas mixture provided to the patient with may influence the measured or estimated patient respiratory parameter (e.g., as respiratory rate). In some cases, as the flow rate reduces, such as to the intermediate flow rates, the measured oxygen concentration value (the fraction of oxygen of the gases flow provided to the patient, for example, the fraction of inspired oxygen

— FiO_2) may increase. If the delivered oxygen concentration is greater than the ambient oxygen concentration (typically 20.9–21.0 %) the off-therapy respiratory estimate should account for this. As such, the step of estimating the off-therapy respiratory parameter of the patient could be extended by including a parameter with a weighting coefficient in order to account for the effect of additional O_2 , as measured by the oxygen concentration sensor or sensors at the operating and/or intermediate flow rates. The parameter may be equal to $(FiO_{2\text{delivered}} - FiO_{2\text{ambient}})$, although other suitable terms accounting for the difference between the O_2 fraction of delivered gases and ambient O_2 (or the effects thereof) can be employed. The parameter (including the weighting coefficient) may accurately account for the effect of above-ambient FiO_2 on patient's respiratory parameter(s).

e) Off-therapy respiratory parameter(s) being estimated by a remote computing device

In some examples, the controller of the respiratory therapy apparatus can be in data communication with one or more remote computing devices and/or servers. In these examples, the remote computing device can perform some or all processing steps of the methods 2400 or 2600 (i.e., steps 2403, 2405, 2406, 2408, 2412 and steps 2603, 2605, 2606, 2608, 2612). For example, the remote computing device(s)/server(s) may be configured to perform any one or more of the following steps: receive flow parameter data at each of the plurality of intermediate flow rates from the controller of the apparatus; and/or estimate or determine a respiratory parameter of the patient at each of the plurality of intermediate flow rates based at least on the received flow parameter data; and/or receive an estimated or determined respiratory parameter of the patient at each of the plurality of intermediate flow rates from the controller of the apparatus; and/or determine or receive an indication of an off therapy respiratory parameter of the patient based at least on the received, or estimated or determined respiratory parameters at each of the plurality of intermediate flow rates.

2.6 Applications of off-therapy respiratory parameter estimations

The determinations or estimates of the off-therapy respiratory parameter(s) made during one or more therapy sessions may be stored. The determinations or estimates of the off-therapy respiratory parameter(s) may be stored in the memory of the controller, and/or in a memory of an external device or server. The determinations or estimates of the off-therapy respiratory parameter(s) may be from a series of therapy sessions. The stored determinations or

estimates of the off-therapy respiratory parameter(s) may allow time-based tracking of trends (and/or other analytics) to be performed. The stored determinations or estimates of the off-therapy respiratory parameter(s) may be processed in order to allow for tracking of trends and/or other analytics. The stored determinations or estimates of the off-therapy respiratory parameter(s) may be processed by the controller of the respiratory therapy apparatus, and/or by the controller of an external device or server. The processed determinations or estimates of the off-therapy respiratory parameter(s) may be further stored as trend data.

The off-therapy respiratory parameter(s), data, or trend data disclosed herein, may be generated and used by the respiratory apparatus in one or more various applications or functions, examples of which are discussed further below.

As discussed, in some configurations, the off-therapy respiratory parameter(s) are generated and used by one or more applications or functions during a respiratory therapy session being undertaken by a patient using the respiratory apparatus. In some configurations, applications or functions may utilise and/or process off-therapy respiratory parameter data generated and stored during a respiratory therapy session, for post-therapy processing and/or storage, such as sending or transmitting the off-therapy respiratory parameter data and/or related therapy data to a remote or cloud computing system — e.g., a patient and/or device management platform.

Examples of various applications and/or functions that may utilise and/or process the off-therapy respiratory parameters discussed above and/or generated by the model(s) disclosed above will now be explained in further detail. In some examples explained further below, the one or more off-therapy respiratory parameters or data may be used for any one or more of the following actions:

Recording off-therapy respiratory parameter(s) and/or ΔRP for each session and transmitting the records to an external (e.g., clinician) device or server, presenting alerts tied to ΔRP to the clinician, and/or displaying ΔRP as part of an adherence monitoring program.

Values could be processed and used to suggest adjustments to the patient's therapy prescription, which may be presented to the patient's clinician. For example, the off-therapy respiratory parameter(s) and/or ΔRP could be analysed to make a recommendation that one or more therapy settings or parameters of the respiratory apparatus be increased or decreased — for example therapy parameters may be any one or more of: the flow rate, pressure level(s), and/or FiO_2 of the flow of gases provided.

Data could be used for titration of therapy settings or parameters of the respiratory apparatus over time, based on the off-therapy respiratory parameter(s) and/or ΔRP . For example, the flow rate or pressure level(s) of the respiratory apparatus could be titrated to optimal levels for therapy efficacy based on estimated off-therapy respiratory parameter(s) and/or ΔRP generated over one or more therapy sessions and/or one or more flow adjustment cycles over each or all of the one or more therapy sessions.

Display of the off-therapy respiratory parameter data and/or off-therapy respiratory parameter trend data on the respiratory apparatus or an associated device — e.g., on a display screen of the apparatus or transmitted for display on an associated device or a device in data communication with the apparatus.

Triggering or generating alarms, notifications, or suggestions (visual, audible, and/or tactile) on the respiratory apparatus or an associated device in data communication with the apparatus, and/or triggering or generating one or more alerts, alarms, and/or notifications based at least partly on the determined off-therapy respiratory parameter data and one or more thresholds. The alerts, alarms, and/or notifications may be audible, visual, and/or tactile.

Triggering or generating one or more alerts, alarms, and/or notifications comprising data indicative of suggested adjustments or changes to therapy settings and/or apparatus settings based at least partly on the off-therapy respiratory parameter data and/or one or more thresholds.

Any one or more of the example applications and/or functions discussed above or below may be used in combination by the respiratory apparatus.

First example application – display of off-therapy respiratory parameter data

In this example, the off-therapy respiratory parameter data generated by the respiratory apparatus may be displayed on a display screen (e.g., graphical user interface – GUI) of the respiratory apparatus, or may be transmitted for display on an associated remote device or system in data communication with the apparatus. As discussed above, the raw or absolute off-therapy respiratory parameter may be displayed, and/or a patient off-therapy respiratory parameter ratio may also be displayed. Additionally, or alternatively, one or more off-therapy respiratory parameter trends or trend data relating to the off-therapy respiratory parameter data (e.g., 'off-therapy respiratory parameter increasing', 'off-therapy respiratory parameter decreasing', 'off-therapy respiratory parameter stable') may be displayed in isolation or concurrently with the off-therapy respiratory parameter indicator data. Further, other information relating to the off-therapy respiratory parameter(s) may also be calculated and displayed. For example, the controller may be configured to compare the estimated or determined off-therapy respiratory parameter(s) relative to a typical or 'healthy' off-therapy respiratory parameter (such as that for the average, or a typical, healthy patient). The controller may be configured to calculate a percentage or ratio of the present off-therapy respiratory parameter(s) relative to the typical or 'healthy' off-therapy parameter. The percentage or ratio may be displayed on the display screen.

The typical or 'healthy' off-therapy respiratory parameter may be a pre-defined construct or benchmark of an off-therapy respiratory parameter, based on experimental data. In other examples, the typical or 'healthy' off-therapy respiratory parameter may be selected from a pre-defined set of values. The typical or 'healthy' off-therapy respiratory parameter may be selected based on the therapy settings (e.g., operating flow rate) and/or other inputs such as the patient's age, sex, height, weight, disease type and/or state, etc.

Second example application – display of notifications and/or suggestions

In this example, the off-therapy respiratory parameter data and/or related notifications and/or suggestions generated or triggered based on working of breathing (WOB) data may be displayed for the user, patient and/or clinicians or clinical staff (e.g., respiratory therapists, nurses etc). The off-therapy respiratory parameter data, notifications, and/or suggestions may be displayed on the display screen (e.g., GUI) of the respiratory apparatus and/or transmitted for display on a remote device or system in data communication with the apparatus.

In one configuration, a display of the respiratory apparatus may be configured to display or present one or more determined off-therapy respiratory parameters based on any of those disclosed above. The determined off-therapy respiratory parameter(s) may be displayed in real-time as they are determined. The display of the off-therapy respiratory parameter(s) may also prompt a user to see if the (e.g., flow rate, pressure level and/or FiO₂ setting(s)) of the respiratory apparatus improve the patient's off-therapy respiratory parameter (e.g., result in a low, lower, or decreasing off-therapy respiratory rate) in real-time. This configuration may enable a user or clinician to fine-tune therapy settings of the respiratory apparatus for the patient with the objective of reducing the patient's off-therapy respiratory parameter.

In another configuration, one or more audible and/or visual alerts, warnings, notifications, prompts or similar may be presented or displayed concurrently with off-therapy respiratory parameters or data on the display screen/GUI. Audible alerts, alarms and/or notifications may be provided via an audio output device of the apparatus. For example, if patient's off-therapy respiratory parameter is increasing/has increased with a new flow rate setting, an appropriate alert may be presented or delivered.

As discussed above, the notification data or information provided in the off-therapy respiratory parameter notifications, alerts, and/or suggestion display screens may be provided or presented in any suitable for or combination of visual forms including, but not limited to, numerical values, textual information, graphical form or formats, continuous trend lines, plotted or graphed data over time, icons, animation, and/or colour-coded information, as examples. Additionally, or alternatively, the notification data may be provided audibly and/or with audible cues or voice commands, for example.

Any of the above notification data (e.g., alerts, notifications, suggestions etc) triggered in response to the calculated or determined off-therapy respiratory parameter data may additionally or alternatively be transmitted for display or presentation on a remote device or system that is in data communication, directly or indirectly, with the respiratory apparatus. Additionally, or alternatively, the off-therapy respiratory parameter data generated by the respiratory apparatus may trigger such notification data to be presented on a remote device or system, e.g., the remote device or system may trigger the display or presentation of the notification data in response to receiving and processing of the off-therapy respiratory parameter data from the respiratory apparatus. By way of example, the remote device or system may be any suitable electronic device or system having a visual (e.g., display screen), audible and/or tactile user interface, including but are not limited to, a mobile phone, smart phone, tablet, laptop, pager, personal computer, wearable device, or any other suitable electronic device.

In some configurations, the off-therapy respiratory parameter data and/or associated triggered notification data may be transmitted by the respiratory apparatus to a remote device or system for presentation. In some configurations, the off-therapy respiratory parameter data and/or associated triggered notification data may be transmitted to a remote cloud or server-based patient and/or device management system, which may process the incoming data and then relay on the off-therapy respiratory parameter and/or notification data to one or more other electronic devices or systems (e.g., clinician electronic devices or systems). In some configurations, the patient and/or device management system may be configured to receive the off-therapy respiratory parameter data from the respiratory apparatus, process the off-therapy respiratory parameter data, and cause (e.g., push, trigger or generate) notification data to be presented on one or more remote electronic devices or systems (e.g., clinician electronic devices or systems).

Third example application – therapy parameter setting adjustment suggestion in response to estimated off-therapy respiratory parameter

In some examples, the controller of the respiratory apparatus may generate a suggestion regarding a therapy parameter or setting adjustment, or may automatically adjust a therapy parameter or setting based on a calculated off-therapy respiratory parameter. In such

examples, the controller may be configured to process and analyse the estimated off-therapy respiratory parameter and generate therapy parameter or setting adjustment recommendations based at least in part on or in response to the off-therapy respiratory parameter. Additionally, or alternatively, the controller may be configured to automatically adjust one or more therapy parameters or settings based at least in part on the estimated off-therapy respiratory parameter. The off-therapy respiratory parameter data could thus be used for titration of optimal therapy settings and/or parameters, such as flow rate settings, over time. In an example, the controller may select and/or adjust the provided operating flow rate of the flow generator so as to maximise the patient's ΔRR , based on the estimated ΔRR (the difference between on and off-therapy respiratory rates). In another example, the controller may select and/or adjust the provided operating flow rate of the flow generator so as to minimise the patient's respiratory rate, based on the estimated off-therapy respiratory rate of the patient.

The titration of therapy settings and/or parameters may also be based on further processing of the off-therapy respiratory parameter data relative to one or more thresholds or similar. The controller may be configured to compare the off-therapy respiratory parameter data to one or more thresholds. If the off-therapy respiratory parameters is outside of one or more configurable thresholds or is otherwise determined as exhibiting a negative trend, then one or more therapy setting or parameter changes may be suggested or triggered. The controller may then be configured to display or present those suggested therapy parameter changes on the display screen of the respiratory apparatus and/or may transmit them for display on one or more remote devices or systems, as discussed above.

Terminology and definitions

The phrases 'computer-readable medium' or 'machine-readable medium' as used in this specification and claims should be taken to include, unless the context suggests otherwise, a single medium or multiple media. Examples of multiple media include a centralised or distributed database and/or associated caches. These multiple media store the one or more sets of computer executable instructions. The phrases 'computer-readable medium' or

'machine-readable medium' should also be taken to include any medium that is capable of storing, encoding or carrying a set of instructions for execution by a processor of a computing device and that cause the processor to perform any one or more of the methods described herein. The computer-readable medium is also capable of storing, encoding or carrying data structures used by or associated with these sets of instructions. The phrases 'computer-readable medium' and 'machine readable medium' include, but are not limited to, portable to fixed storage devices, solid-state memories, optical media or optical storage devices, magnetic media, and/or various other mediums capable of storing, containing or carrying instruction(s) and/or data. The 'computer-readable medium' or 'machine-readable medium' may be non-transitory.

The term 'comprising' as used in this specification and claims means 'consisting at least in part of' or 'including, but not limited to' such that it is to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense. When interpreting each statement in this specification and claims that includes the term "comprising", features other than that or those prefaced by the term may also be present. Related terms such as "comprise" and "comprises" are to be interpreted in the same manner.

It is intended that reference to a range of numbers disclosed herein (for example, 1 to 10) also incorporates reference to all rational numbers within that range (for example, 1, 1.1, 2, 3, 3.9, 4, 5, 6, 6.5, 7, 8, 9 and 10) and also any range of rational numbers within that range (for example, 2 to 8, 1.5 to 5.5 and 3.1 to 4.7) and, therefore, all sub-ranges of all ranges expressly disclosed herein are hereby expressly disclosed. These are only examples of what is specifically intended and all possible combinations of numerical values between the lowest value and the highest value enumerated are to be considered to be expressly stated in this application in a similar manner.

The term 'and/or' means 'and' or 'or', or both.

The use of '(s)' following a noun means the plural and/or singular forms of the noun.

Conditional language, such as “can,” “could,” “might,” or “may,” unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements, and/or steps. Thus, such conditional language is not generally intended to imply that features, elements, and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements, and/or steps are included or are to be performed in any particular embodiment.

Language of degree used herein, such as the terms “approximately,” “about,” “generally,” and “substantially” as used herein represent a value, amount, or characteristic close to the stated value, amount, or characteristic that still performs a desired function or achieves a desired result. For example, the terms “approximately,” “about,” “generally,” and “substantially” may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

In the above description, specific details are given to provide a thorough understanding of the embodiments. However, it will be understood by one of ordinary skill in the art that the embodiments may be practiced without these specific details. For example, software modules, functions, circuits, etc., may be shown in block diagrams in order not to obscure the embodiments in unnecessary detail. In other instances, well-known modules, structures and techniques may not be shown in detail in order not to obscure the embodiments.

Also, it is noted that the embodiments may be described as a process that is depicted as a flowchart, a flow diagram, a structure diagram, or a block diagram. Although a flowchart may

describe the operations as a sequential process, many of the operations can be performed in parallel or concurrently. In addition, the order of the operations may be rearranged. A process is terminated when its operations are completed. A process may correspond to a method, a function, a procedure, a subroutine, a subprogram, etc., in a computer program. When a process corresponds to a function, its termination corresponds to a return of the function to the calling function or a main function.

Aspects of the systems and methods described above may be operable on any type of general purpose computer system or computing device, including, but not limited to, a desktop, laptop, notebook, tablet, smart television, gaming console, or mobile device. The term "mobile device" includes, but is not limited to, a wireless device, a mobile phone, a smart phone, a mobile communication device, a user communication device, personal digital assistant, mobile hand-held computer, a laptop computer, wearable electronic devices such as smart watches and head-mounted devices, an electronic book reader and reading devices capable of reading electronic contents and/or other types of mobile devices typically carried by individuals and/or having some form of communication capabilities (e.g., wireless, infrared, short-range radio, cellular etc.).

Aspects of the systems and methods described above may be operable or implemented on any type of specific-purpose or special computer, or any machine or computer or server or electronic device with a microprocessor, processor, microcontroller, programmable controller, or the like, or a cloud-based platform or other network of processors and/or servers, whether local or remote, or any combination of such devices.

Furthermore, embodiments may be implemented by hardware, software, firmware, middleware, microcode, or any combination thereof. When implemented in software, firmware, middleware or microcode, the program code or code segments to perform the necessary tasks may be stored in a machine-readable medium such as a storage medium or other storage(s). A processor may perform the necessary tasks. A code segment may represent a procedure, a function, a subprogram, a program, a routine, a subroutine, a module, a software package, a class, or any combination of instructions, data structures, or program statements. A code segment may be coupled to another code segment or a

hardware circuit by passing and/or receiving information, data, arguments, parameters, or memory contents. Information, arguments, parameters, data, etc. may be passed, forwarded, or transmitted via any suitable means including memory sharing, message passing, token passing, network transmission, etc.

In the above description, a storage medium may represent one or more devices for storing data, including read-only memory (ROM), random access memory (RAM), magnetic disk storage mediums, optical storage mediums, flash memory devices and/or other machine or computer readable mediums for storing information.

The various illustrative logical blocks, modules, circuits, elements, and/or components described in connection with the examples disclosed herein may be implemented or performed with a general purpose processor, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic component, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A general purpose processor may be a microprocessor, but in the alternative, the processor may be any conventional processor, controller, microcontroller, circuit, and/or state machine. A processor may also be implemented as a combination of computing components, e.g., a combination of a DSP and a microprocessor, a number of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration.

The methods or algorithms described in connection with the examples disclosed herein may be embodied directly in hardware, in a software module executable by a processor, or in a combination of both, in the form of processing unit, programming instructions, or other directions, and may be contained in a single device or distributed across multiple devices. A software module may reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD- ROM, or any other form of storage medium known in the art. A storage medium may be coupled to the processor such that the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium may be integral to the processor.

One or more of the components and functions illustrated the figures may be rearranged and/or combined into a single component or embodied in several components without departing from the scope of the disclosure. Additional elements or components may also be added without departing from the scope of the disclosure. Additionally, the features described herein may be implemented in software, hardware, as a business method, and/or combination thereof.

In its various aspects, embodiments of the disclosure can be embodied in a computer-implemented process, a machine (such as an electronic device, or a general purpose computer or other device that provides a platform on which computer programs can be executed), processes performed by these machines, or an article of manufacture. Such articles can include a computer program product or digital information product in which a computer readable storage medium containing computer program instructions or computer readable data stored thereon, and processes and machines that create and use these articles of manufacture.

Although this disclosure has been described in the context of certain embodiments and examples, it will be understood by those skilled in the art that the disclosure extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. In addition, while several variations of the embodiments of the disclosure have been shown and described in detail, other modifications, which are within the scope of this disclosure, will be readily apparent to those of skill in the art. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the disclosure. For example, features described above in connection with one embodiment can be used with a different embodiment described herein and the combination still fall within the scope of the disclosure. It should be understood that various features and aspects of the disclosed embodiments can be combined with, or substituted for, one another in order to form varying modes of the embodiments of the disclosure. Thus, it is intended that the scope of the disclosure herein should not be limited by the particular embodiments described above. Accordingly, unless otherwise stated, or unless clearly incompatible, each embodiment of this disclosure may comprise, additional to its essential features described herein, one or

more features as described herein from each other embodiment of the invention disclosed herein.

This disclosure may also be said broadly to consist in the parts, elements and features referred to or indicated in this disclosure, individually or collectively, and any or all combinations of any two or more said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this disclosure relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described in this section or elsewhere in this specification unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

Furthermore, certain features that are described in this disclosure in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations, one or more features from a claimed combination can, in some cases, be excised from the combination, and the combination may be claimed as a subcombination or variation of a subcombination.

Moreover, while operations may be depicted in the drawings or described in the specification in a particular order, such operations need not be performed in the particular order shown or in sequential order, or that all operations be performed, to achieve desirable results. Other operations that are not depicted or described can be incorporated in the example methods and processes. For example, one or more additional operations can be performed before, after, simultaneously, or between any of the described operations. Further, the operations may be rearranged or reordered in other implementations. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated and/or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure. Also, the separation of various system components in the implementations described above should not be understood as requiring such separation in all implementations, and it should be understood that the described components and systems can generally be integrated together in a single product or packaged into multiple products.

For purposes of this disclosure, certain aspects, advantages, and novel features are described herein. Not necessarily all such advantages may be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the disclosure may be embodied or carried out in a manner that achieves one advantage or a group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

The scope of the present disclosure is not intended to be limited by the specific disclosures of embodiments in this section or elsewhere in this specification, and may be defined by claims as presented in this section or elsewhere in this specification or as presented in the future. The language of the claims is to be interpreted broadly based on the language employed in the claims and not limited to the examples described in the present specification or during the prosecution of the application, which examples are to be construed as non-exclusive.

CLAIMS

1. A method of estimating an off-therapy respiratory parameter of a patient during therapy, the method comprising:
 - providing a flow of gases at a plurality of flow rates via a flow generator, the flow rates comprising at least an operating flow rate and one or more intermediate flow rates;
 - receiving flow parameter data indicative or representative of one or more properties of the flow of gases provided by the flow generator at each of the plurality of flow rates from one or more sensors;
 - estimating or determining a respiratory parameter of the patient at each of the plurality of flow rates, based at least in part on the flow parameter data received; and
 - estimating an off-therapy respiratory parameter of the patient based at least in part on the estimated or determined respiratory parameters at each of the plurality of flow rates.
2. A method according to claim 1, wherein the flow parameter data comprises flow rate data indicative or representative of the flow rate of the flow of gases provided by the flow generator.
3. A method according to claim 1 or claim 2, wherein the flow parameter data comprises pressure data indicative or representative of the pressure of the flow of gases provided by the flow generator.
4. A method according to any one of claims 1 to 3, wherein the step of estimating or determining the respiratory parameter of the patient at each of the plurality of flow rates comprises assessing the flow parameter data.
5. A method according to any of the preceding claims, wherein the respiratory parameter of the patient is the respiratory rate of the patient.

6. A method according to any one of claims 1 to 4, wherein the respiratory parameter of the patient is the inspiratory-expiratory time ratio of the patient.
7. A method according to claim 5, wherein the step of estimating or determining the respiratory rate of the patient at each of the plurality of flow rates comprises:
 - performing a frequency analysis of the flow parameter data at an intermediate flow rate;
 - identifying a plurality of local maxima of a signal resulting from the frequency analysis; and
 - outputting a frequency corresponding to a frequency component with the highest magnitude among the plurality of local maxima as an estimated respiratory rate of the patient.
8. A method according to any of the preceding claims, wherein the operating flow rate comprises a therapeutic flow rate.
9. A method according to claim 8, wherein the one or more intermediate flow rates comprise one or more sub-therapeutic flow rates, and wherein the one or more sub-therapeutic flow rates are lower than the operating flow rate.
10. A method according to any one of the preceding claims, wherein the step of providing the flow of gases at a plurality of flow rates comprises, at one or more time intervals, adjusting the flow rate to a different intermediate flow rate.
11. A method according to claim 10, wherein the step of estimating or determining a respiratory parameter of the patient occurs at each time interval.
12. A method according to claim 10 or claim 11, wherein the intermediate flow rate is reduced at each time interval.
13. A method according to any one of the preceding claims, wherein an intermediate flow rate may comprise a minimum flow rate.

14. A method according to any one of claims 10 to 13, wherein adjusting the flow rate to a different intermediate flow rate comprises ramping the flow rate gradually from the present flow rate to the different intermediate flow rate.
15. A method according to any one of the preceding claims, wherein the flow rate is maintained for a minimum or predetermined period of time at each of the one or more intermediate flow rates, before the step of estimating or determining a respiratory parameter of the patient at each flow rate occurs.
16. A method according to claim 15, wherein the minimum or predetermined period of time is inversely proportional to an estimated respiratory parameter of the patient.
17. A method according to claim 15 or claim 16, wherein the minimum or predetermined period of time is at least long enough to enable residual effects of the previous flow rate on the respiratory parameter of the patient to decay.
18. A method according to any one of the preceding claims, wherein the method further comprises returning to the operating flow rate after the step of estimating an off-therapy respiratory parameter of the patient.
19. A method according to claim 18, wherein the returning to the operating flow rate comprises first increasing the flow rate to one or more intermediate flow rates.
20. A method according to claim 19, wherein the flow rate is increased to one or more intermediate flow rates at gradual intervals before returning to the operating flow rate.
21. A method according to any one of the preceding claims, wherein the method further comprises the steps of:
 - receiving flow parameter data at the operating flow rate; and
 - estimating or determining a respiratory parameter of the patient at the operating flow rate based at least on the flow parameter data.

22. A method according to claim 21, wherein the step of estimating an off-therapy respiratory parameter of the patient is based at least on the estimated or determined respiratory parameters at each of the one or more intermediate flow rates and at the operating flow rate.
23. A method according to any one of the preceding claims, wherein the flow parameter data comprises oxygen concentration data indicative or representative of the concentration of oxygen of the flow of gases provided by the flow generator.
24. A method according to any one of the preceding claims, wherein estimating an off-therapy respiratory parameter of the patient is further based on at least the flow rate data received at each of the plurality of flow rates.
25. A method according to claim 24, wherein estimating an off-therapy respiratory parameter of the patient is further based on the oxygen concentration data received at each of the plurality of intermediate flow rates.
26. A method according to any one of the preceding claims, wherein the step of estimating the off-therapy respiratory parameter of the patient is performed by a model, wherein the model takes as input at least the estimated or determined respiratory parameters at each of the plurality of flow rates.
27. A method according to claim 26, wherein the model further takes as input the flow parameter data.
28. A method according to claim 27, wherein the model further takes as input the flow parameter data received at the operating flow rate and the flow data received at the one or more intermediate flow rates.
29. A method according to any one of claims 26 to 28, wherein the model is a linear model and comprises coefficients that define a relationship between the inputted estimated or determined respiratory parameters and the flow parameter data at each flow rate.

30. A method according to any one of claims 26 to 29, wherein the model further comprises parameters that relate the estimated or determined respiratory parameter and the flow parameter data at each flow rate.
31. A method according to claim 30, wherein the parameters of the model comprise at least one or more of:
- an average of the estimated or determined respiratory parameter of the patient at each of the plurality of flow rates;
 - a difference between the operating flow rate and a/the minimum flow rate;
 - a difference between the respiratory parameter of the patient at the operating flow rate and an average of the estimated or determined respiratory parameter of the patient at each of the one or more intermediate flow rates, wherein the difference is divided by a difference between the operating flow rate and the one or more intermediate flow rates;
 - a difference between the oxygen concentration data of the flow of gases at one or more intermediate flow rates and an ambient reading of oxygen concentration level.
32. A method according to any one of claims 26 to 31, wherein the model is configured to output a value corresponding to an estimation of the respiratory parameter of the patient if the flow generator was providing no flow.
33. A method according to any one of claims 26 to 32, wherein the model is configured to output a value relating an expected change in the respiratory parameter of the patient based on a change in flow rate.
34. A method according to any one of claims 26 to 28, wherein the model comprises a fitted linear equation, wherein the fitted linear equation takes as input the estimates of a respiratory parameter of the patient at each flow rate, and measurements of said flow rates.

35. A method according to claim 34, wherein the fitted linear equation extrapolates the respiratory parameter of the patient based on an input of the estimated or determined respiratory parameter at each of the plurality of intermediate flow rates.
36. A method according to claim 34 or claim 35, wherein the fitted linear equation is configured to output an extrapolated respiratory parameter of the patient based on an input of at least the estimated or determined respiratory parameter determined at each of the plurality of flow rates.
37. A method according to claim 36, wherein the extrapolated respiratory parameter of the patient is an approximation of the respiratory parameter of the patient at a flow rate below at least the lowest intermediate flow rate.
38. A method according to claim 33, wherein the value outputted relates an expected change in the respiratory parameter of the patient to an increase in flow rate from zero to a pre-determined operating flow rate for therapeutic flow rate.
39. A method according to any one of the preceding claims, wherein the off-therapy respiratory parameter of the patient is estimated while the respiratory therapy system is providing a flow of gases to the airway of the patient.
40. A method according to any one of the preceding claims, wherein the method further comprises determining a difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient.
41. A method according to claim 40, wherein the determination of the difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient is further based on one or more average values of off-therapy respiratory parameter of the patient determined over multiple therapy sessions and/or multiple flow rate reduction and respiratory parameter estimation cycles over one therapy session.

42. A method according to any one of the preceding claims, wherein the method further comprises determining a status of the patient's respiratory parameter based on the flow parameter data.
43. A method according to any one of the preceding claims, wherein the method further comprises controlling the flow generator to provide the flow of gases at the plurality of intermediate flow rates based on the status of the patient's respiratory parameter indicating that the patient's respiratory parameter is substantially stable.
44. A method according to claim 43, wherein the step of determining the status of the patient's respiratory parameter comprises:
- determining an indication or estimate of the respiratory parameter of the patient based on flow parameter data received at a plurality of intervals while at the operating flow rate, and
 - comparing the indication or estimate of the respiratory parameter of the patient at each interval to at least the indication or estimate of the respiratory parameter of the patient at one or more previous intervals.
45. A method according to claim 43 or claim 44, wherein the status of the patient's respiratory parameter relates to a degree or amount of change between the indication or estimate of the respiratory parameter of the patient determined at a present interval to the indication or estimate of the respiratory parameter of the patient determined at one or more previous intervals, based on said comparison.
46. A method according to any one of the preceding claims wherein the method further comprises sending or transmitting data representing the estimated off-therapy respiratory parameter of the patient to an external device via a data communication protocol.
47. A method according to any one of the preceding claims wherein the method further comprises adjusting one or more parameters of or associated with the flow generator based at least partly on the estimated off-therapy respiratory parameter of the patient.

48. A method according to any one of the preceding claims wherein the method further comprises generating or providing suggested thresholds and/or parameters associated with the one or more thresholds based at least partly on the estimated off-therapy respiratory parameter of the patient.
49. A method according to claim 48, wherein the method further comprises generating an alert, alarm, and/or notification comprising data indicative of suggested adjustments to one or more therapy settings based at least partly on the estimated off-therapy respiratory parameter of the patient, and one or more thresholds.
50. A method according to claim 49, wherein the therapy settings comprise a flow rate setting and/or an FiO₂ setting.
51. A method according to any one of the preceding claims, wherein the method is configured for use in a non-sealed respiratory therapy system.
52. A method according to any one of the preceding claims, wherein the method is configured for use in the delivery of a nasal high flow therapy.
53. A respiratory apparatus configured to provide a flow of gases to a patient, comprising:
- a flow generator configured to generate the flow of gases for the patient at a plurality of flow rates;
 - one or more sensors each configured to generate flow parameter data indicative or representative of one or more properties of the flow of gases;
 - and
 - a controller, wherein the controller is configured to:
 - control the flow generator to provide a flow of gases at the plurality of flow rates, the plurality of flow rates comprising least at an operating flow rate and one or more intermediate flow rates;
 - receive flow parameter data from the one or more sensors at each of the plurality of flow rates;

estimate or determine a respiratory parameter of the patient at each of the plurality of flow rates based at least in part on the flow parameter data received; and

estimate an off-therapy respiratory parameter of the patient based at least in part on the estimated or determined respiratory parameter determined at each of the plurality of flow rates.

54. A respiratory apparatus according to claim 53, wherein the flow parameter data comprises flow rate data indicative or representative of the flow rate of the flow of gases provided by the flow generator.
55. A respiratory apparatus according to claim 53 or claim 54, wherein the flow parameter data comprises pressure data indicative or representative of the pressure of the flow of gases at an outlet of the blower of the flow generator.
56. A respiratory apparatus according to any one of claims 53 to 55, wherein the controller is configured to estimate or determine the respiratory parameter of the patient at each of the plurality of flow rates by assessing the flow parameter data.
57. A respiratory apparatus according to any one of claims 53 to 56, wherein the respiratory parameter of the patient is a respiratory rate of the patient.
58. A respiratory apparatus according to any one of claims 53 to 56, wherein the respiratory parameter of the patient is an inspiratory-expiratory time ratio of the patient.
59. A respiratory apparatus according to claim 57, wherein the controller is configured to estimate or determine the respiratory rate of the patient at each of the plurality of flow rates, by:
- performing a frequency analysis of the flow parameter data at an intermediate flow rate;
 - identifying a plurality of local maxima of a signal resulting from the frequency analysis; and

outputting a frequency corresponding to a frequency component with the highest magnitude among the plurality of local maxima as an estimated respiratory rate of the patient.

60. A respiratory apparatus according to any one of claims 53 to 59, wherein the operating flow rate comprises a therapeutic flow rate.
61. A respiratory apparatus according to claim 60, wherein the one or more intermediate flow rates comprise one or more sub-therapeutic flow rates, and wherein the one or more sub-therapeutic flow rates are lower than the operating flow rate.
62. A respiratory apparatus according to any one of claims 53 to 61, wherein the controller is configured to control the flow generator to provide the flow of gases at a plurality of flow rates by, at one or more time intervals, adjusting the flow rate to a different intermediate flow rate.
63. A respiratory apparatus according to claim 62, wherein the controller is configured to estimate or determine a respiratory parameter of the patient at each time interval.
64. A respiratory apparatus according to claim 62 or claim 63, wherein the intermediate flow rate at each time interval is reduced at each time interval.
65. A respiratory apparatus according to any one of claims 53 to 64, wherein an intermediate flow rate may comprise a minimum flow rate.
66. A respiratory apparatus according to any one of claims 62 to 65, wherein adjusting the flow rate to a different intermediate flow rate comprises ramping the flow rate gradually from the present flow rate to the different intermediate flow rate.
67. A respiratory apparatus according to any one of claims 53 to 66, wherein the controller is configured to maintain the flow rate for a minimum or predetermined period of time at each of the one or more intermediate flow rates, before estimating or determining a respiratory parameter of the patient at each flow rate.

68. A respiratory apparatus according to claim 67, wherein the predetermined period of time is inversely proportional to an estimated respiratory parameter of the patient.
69. A respiratory apparatus according to claim 67 or claim 68, wherein the predetermined period of time is at least long enough to enable residual effects of the previous flow rate on the respiratory parameter of the patient to decay.
70. A respiratory apparatus according to any one of claims 53 to 69, wherein the controller is further configured to control the flow generator to return to the operating flow rate after estimating an off-therapy respiratory parameter of the patient.
71. A respiratory apparatus according to claim 70, wherein the returning to the operating flow rate comprises first increasing the operating flow rate to one or more intermediate flow rates.
72. A respiratory apparatus according to claim 71, wherein the operating flow rate is increased to one or more intermediate flow rates at gradual intervals before returning to the operating flow rate.
73. A respiratory apparatus according to any one of claims 53 to 72, wherein the controller is further configured to:
- receive flow parameter data at the operating flow rate; and
 - estimate or determine a respiratory parameter of the patient at the operating flow rate based at least on said flow parameter data.
74. A respiratory apparatus according to claim 73, wherein the controller is configured to estimate an off-therapy respiratory parameter of the patient based at least on the estimated or determined respiratory parameters at each of the one or more intermediate flow rates and at the operating flow rate.

75. A respiratory apparatus according to any one of claims 53 to 74, wherein the flow parameter data comprises oxygen concentration data indicative or representative of the concentration of oxygen of the flow of gases provided by the flow generator.
76. A respiratory apparatus according to any one of claims 53 to 75, wherein the controller is configured to estimate an off-therapy respiratory parameter of the patient based on at least the flow rate data received at each of the plurality of flow rates.
77. A respiratory apparatus according to claim 76, wherein the controller is configured to estimate an off-therapy respiratory parameter of the patient further based on the oxygen concentration data received at each of the plurality of intermediate flow rates.
78. A respiratory apparatus according to any one of claims 53 to 77, wherein the controller is configured to estimate the off-therapy respiratory parameter of the patient using a model, wherein the model takes as input at least the estimated or determined respiratory parameters at each of the plurality of flow rates.
79. A respiratory apparatus according to claim 78, wherein the model further takes as input the flow parameter data.
80. A respiratory apparatus according to claim 79, wherein the model further takes as input the flow parameter data received at the operating flow rate and the flow data received at the one or more intermediate flow rates.
81. A respiratory apparatus according to any one of claims 78 to 80, wherein the model is a linear model and comprises coefficients that define a relationship between the inputted estimated or determined respiratory parameters and the flow parameter data at each flow rate.
82. A respiratory apparatus according to any one of claims 78 to 81, wherein the model further comprises parameters that relate the estimated or determined respiratory parameter and the flow parameter data at each flow rate.

83. A respiratory apparatus according to claim 82, wherein the parameters of the model comprise at least one or more of:
- an average of the estimated or determined respiratory parameter of the patient at each of the plurality of flow rates;
 - a difference between the operating flow rate and a/the minimum flow rate;
 - a difference between the respiratory parameter of the patient at the operating flow rate and an average of the estimated or determined respiratory parameter of the patient at each of the one or more intermediate flow rates, wherein the difference is divided by a difference between the operating flow rate and the one or more intermediate flow rates;
 - a difference between the oxygen concentration data of the flow of gases at one or more intermediate flow rates and an ambient reading of oxygen concentration level.
84. A respiratory apparatus according to any one of claims 78 to 83, wherein the model is configured to output a value corresponding to an estimation of the respiratory parameter of the patient if the respiratory therapy apparatus was providing no flow.
85. A respiratory apparatus according to any one of claims 78 to 84, wherein the model is configured to output a value relating an expected change in the respiratory parameter of the patient based on a change in flow rate.
86. A respiratory apparatus according to any one of claims 78 to 80, wherein the model comprises a fitted linear equation, wherein the fitted linear equation takes as input the estimates of a respiratory parameter of the patient at each flow rate, and measurements of said flow rates.
87. A respiratory apparatus according to claim 86, wherein the fitted linear equation extrapolates the respiratory parameter of the patient based on an input of the estimated or determined respiratory parameter at each of the plurality of intermediate flow rates.

88. A respiratory apparatus according to claim 86 or claim 87, wherein the fitted linear equation is configured to output an extrapolated respiratory parameter of the patient based on an input of at least the estimated or determined respiratory parameter determined at each of the plurality of flow rates.
89. A respiratory apparatus according to claim 88, wherein the extrapolated respiratory parameter of the patient is an approximation of the respiratory parameter of the patient at a flow rate below at least the lowest intermediate flow rate.
90. A respiratory apparatus according to claim 85, wherein the value outputted relates an expected change in the respiratory parameter of the patient to an increase in flow rate from zero to a pre-determined operating flow rate for therapeutic flow rate.
91. A respiratory apparatus according to any one of claims 53 to 90, wherein the off-therapy respiratory parameter of the patient is estimated while the patient is using the respiratory apparatus for therapeutic purposes.
92. A respiratory apparatus according to any one of claims 53 to 91, wherein the controller is further configured to determine a difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient.
93. A respiratory apparatus according to claim 92, wherein the determination of the difference between the estimated or determined respiratory parameter of the patient at the operating flow rate and the estimated off-therapy respiratory parameter of the patient is further based on one or more average values of off-therapy respiratory parameter of the patient determined over multiple therapy sessions and/or multiple flow rate reduction and respiratory parameter estimation cycles over one therapy session.
94. A respiratory apparatus according to any one of claims 53 to 93, wherein the controller is further configured to determine a status of the patient's respiratory parameter based on the flow parameter data.

95. A respiratory apparatus according to any one of claims 53 to 94, wherein the controller is further configured to control the flow generator to provide the flow of gases at the plurality of intermediate flow rates based on the status of the patient's respiratory parameter indicating that the patient's respiratory parameter is substantially stable.
96. A respiratory apparatus according to claim 95, wherein the controller is configured to determine the status of the patient's respiratory parameter by:
- determining an indication or estimate of the respiratory parameter of the patient based on flow parameter data received at a plurality of intervals while at the operating flow rate, and
 - comparing the indication or estimate of the respiratory parameter of the patient at each interval to at least the indication or estimate of the respiratory parameter of the patient at one or more previous intervals.
97. A respiratory apparatus according to claim 95 or claim 96, wherein the status of the patient's respiratory parameter relates to a degree of change between the indication or estimate of the respiratory parameter of the patient determined at a present interval to the indication or estimate of the respiratory parameter of the patient determined at one or more previous intervals, based on said comparison.
98. A respiratory apparatus according to any one of claims 53 to 97, wherein the controller is further configured to transmit data representing the estimated off-therapy respiratory parameter of the patient to a device or system that is in data communication with the apparatus.
99. A respiratory apparatus according to any one of claims 53 to 98, wherein the controller is further configured to adjust one or more parameters of the respiratory apparatus based at least partly on the estimated off-therapy respiratory parameter of the patient.
100. A respiratory apparatus according to any one of claims 53 to 99, wherein the controller is further configured to generate suggested thresholds and/or parameters

associated with the one or more thresholds based at least partly on the estimated off-therapy respiratory parameter of the patient.

101. A respiratory apparatus according to claim 100, wherein the controller is further configured to generate an alert, alarm, and/or notification comprising data indicative of suggested adjustments to one or more therapy settings based at least partly on the estimated off-therapy respiratory parameter of the patient, and one or more thresholds.
102. A respiratory apparatus according to claim 101, wherein the therapy settings comprise a flow rate setting and/or an FiO_2 setting.
103. The respiratory apparatus of any one of claims 53 to 102, wherein the respiratory apparatus is configured for use in a non-sealed respiratory therapy system.
104. The respiratory apparatus of any one of claims 53 to 103, wherein the respiratory apparatus is configured for use in the delivery of a nasal high flow therapy.
105. The respiratory apparatus of claim 103, wherein the non-sealed respiratory therapy system comprises:
 - a breathing conduit operatively coupled to the flow generator and configured to convey the flow of gases from the flow generator to the user;
 - a patient interface operatively coupled to the breathing conduit; and
 - the respiratory apparatus of any one of claims 53 to 102.
106. A method according to claim 34, or a respiratory apparatus according to claim 86, wherein the fitted linear equation takes the form of a series of linear terms.
107. A respiratory therapy apparatus configured to provide a flow of gases to a user, comprising:
 - a flow generator configured to provide a flow of gases according to one or more therapy parameters, the one or more therapy parameters comprising at least an operating flow rate;

one or more sensors each configured to generate flow parameter data indicative or representative of one or more properties of the flow of gases; and

a controller, wherein the controller is configured to:

receive the flow parameter data from the one or more sensors, determine or receive an indication of an off-therapy respiratory parameter of the patient, the indication of the off-therapy respiratory parameter determined based at least in part on the flow parameter data, and adjust one or more of the therapy parameters based on the indication of an off-therapy respiratory parameter of the patient.

108. The respiratory therapy apparatus according to claim 108, wherein the controller is configured to determine an indication of an off-therapy respiratory parameter of the patient by

controlling the flow generator to provide a flow of gases at the plurality of flow rates, the plurality of flow rates comprising least at an operating flow rate and one or more intermediate flow rates;

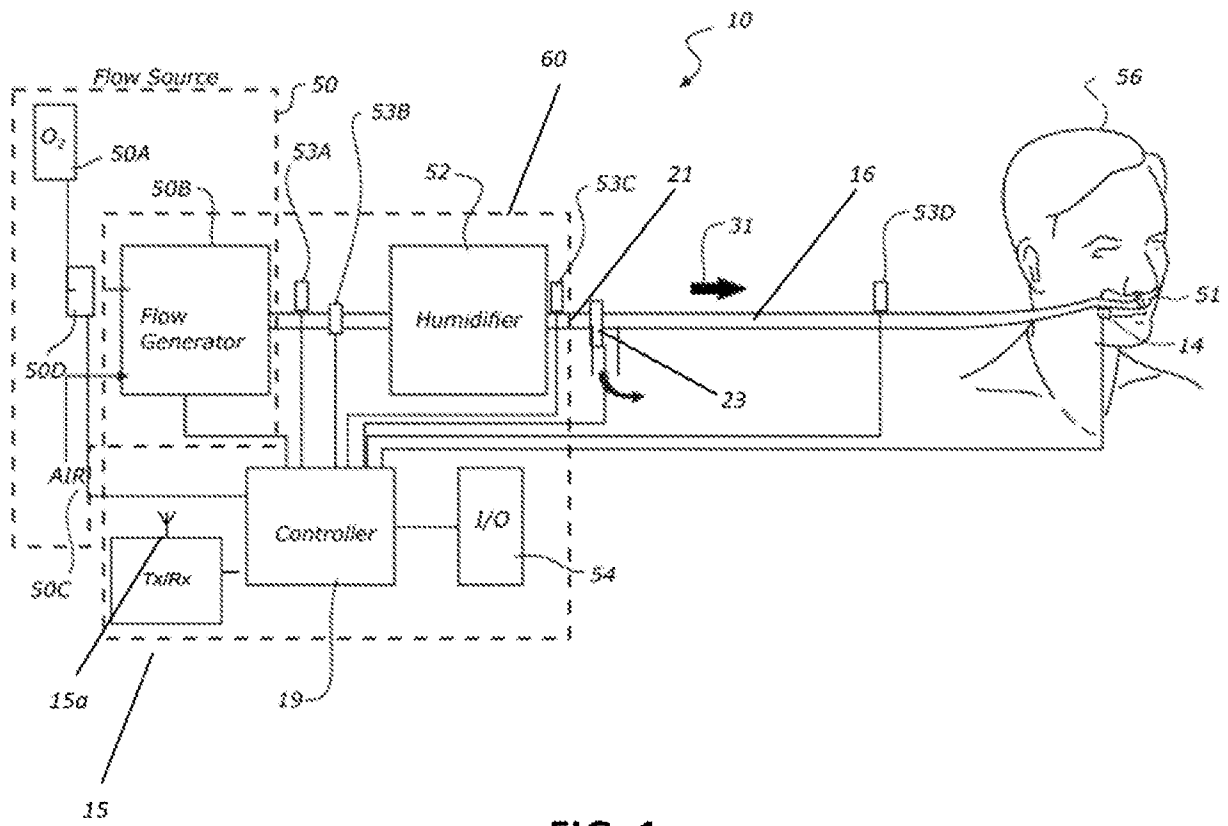
estimating or determining a respiratory parameter of the patient at each of the plurality of flow rates based at least in part on the flow parameter data received; and

estimating an off-therapy respiratory parameter of the patient based at least in part on the estimated or determined respiratory parameter determined at each of the plurality of flow rates.

109. A respiratory apparatus according to claim 109, wherein the flow parameter data comprises flow rate data indicative or representative of the flow rate of the flow of gases provided by the flow generator.

110. A respiratory apparatus according to claim 109 or claim 110, wherein the respiratory parameter of the patient is a respiratory rate of the patient.

111. A respiratory apparatus according to claim 109 or claim 110, wherein the respiratory parameter of the patient is an inspiratory-expiratory time ratio of the patient.
112. A respiratory apparatus according to any one of claims 109 to 112, wherein the operating flow rate comprises a therapeutic flow rate.
113. A respiratory apparatus according to claim 113, wherein the one or more intermediate flow rates comprise one or more sub-therapeutic flow rates, and wherein the one or more sub-therapeutic flow rates are lower than the operating flow rate.
114. A respiratory apparatus according to any one of claims 109 to 114, wherein the controller is further configured to:
- receive flow parameter data at the operating flow rate; and
 - estimate or determine a respiratory parameter of the patient at the operating flow rate based at least on said flow parameter data.
115. A respiratory apparatus according to claim 115, wherein the controller is configured to estimate an off-therapy respiratory parameter of the patient based at least on the estimated or determined respiratory parameters at each of the one or more intermediate flow rates and at the operating flow rate.
116. A respiratory apparatus according to any one of claims 109 to 116, wherein the controller is configured to estimate an off-therapy respiratory parameter of the patient based on at least the flow rate data received at each of the plurality of flow rates.
117. A respiratory apparatus according to any one of claims 109 to 117, wherein the off-therapy respiratory parameter of the patient is estimated while the patient is using the respiratory apparatus for therapeutic purposes.
118. A respiratory apparatus according to any one of claims 108 to 118, wherein the one or more of the therapy parameters comprise a flow rate setting and/or an FiO_2 setting.



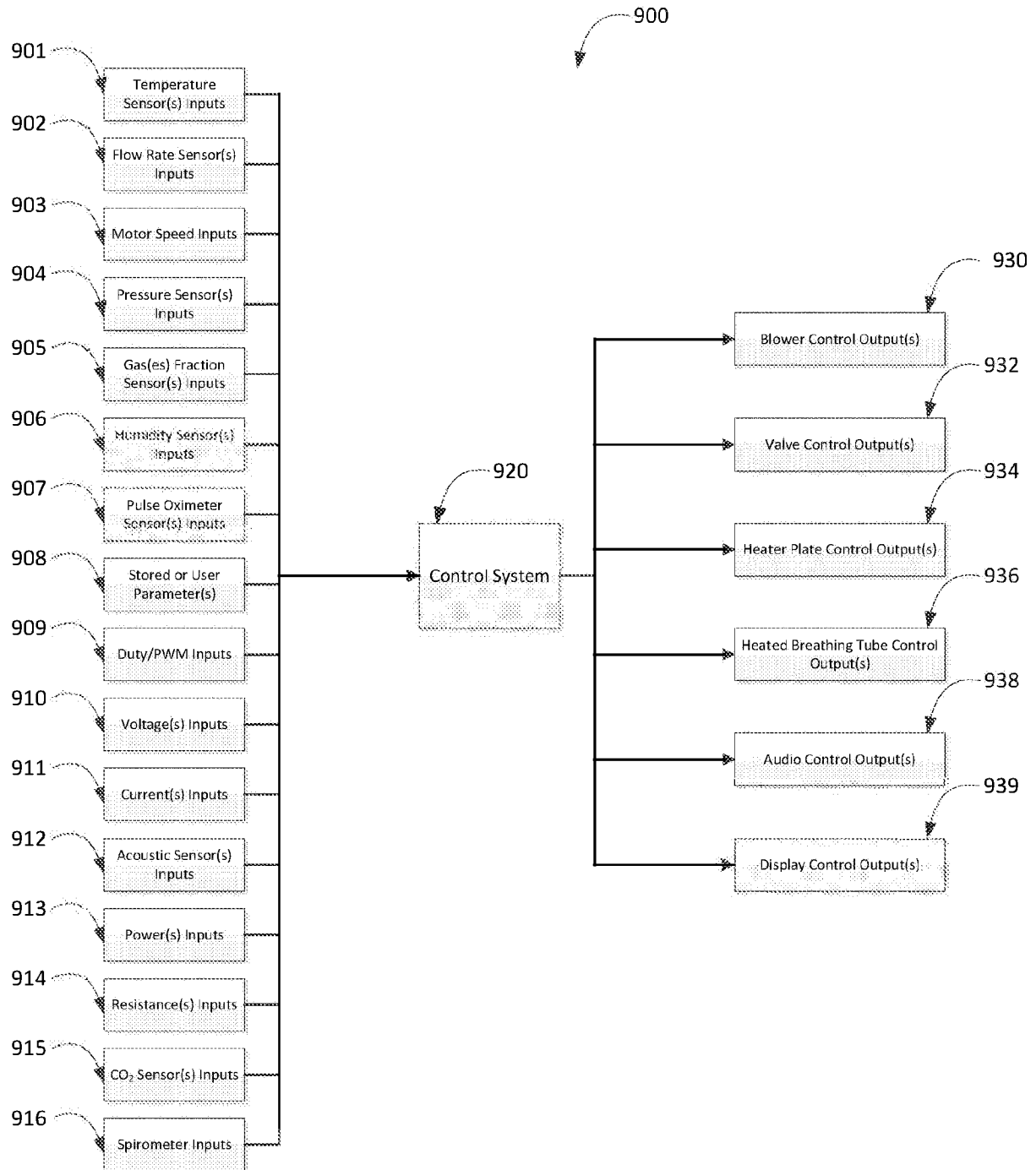
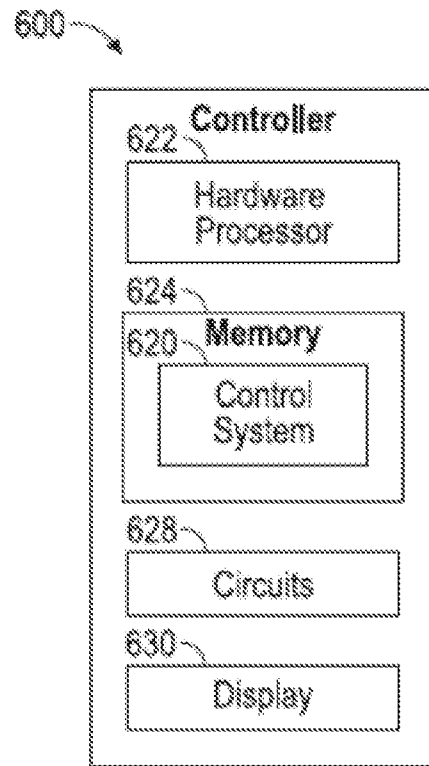


FIG. 2

**FIG. 3**

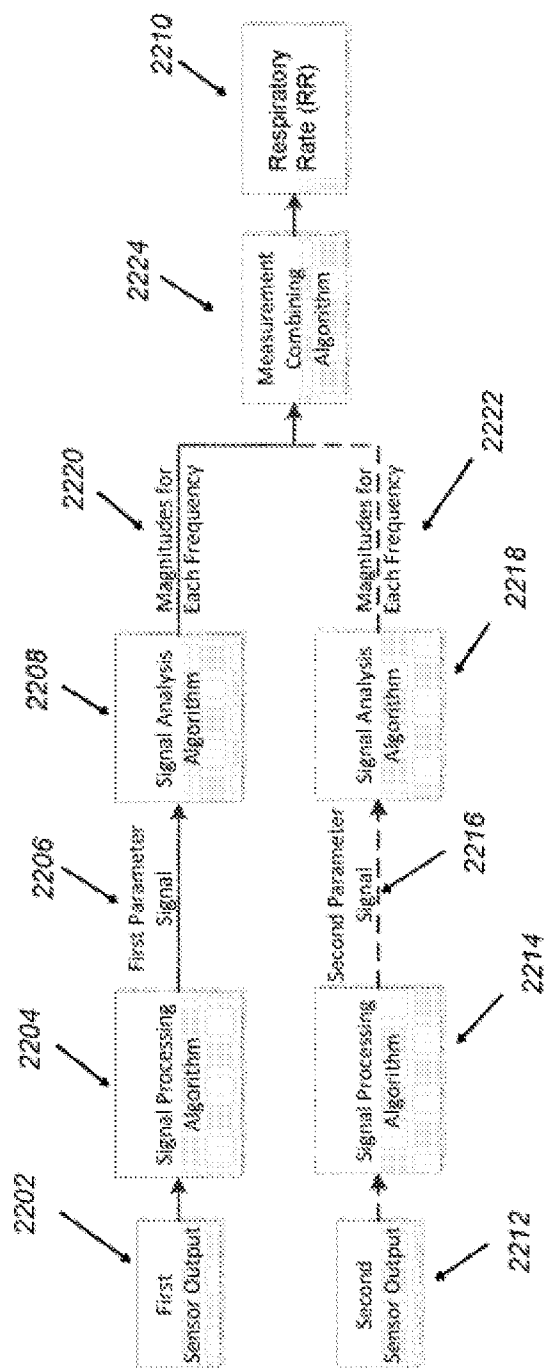


FIG. 4

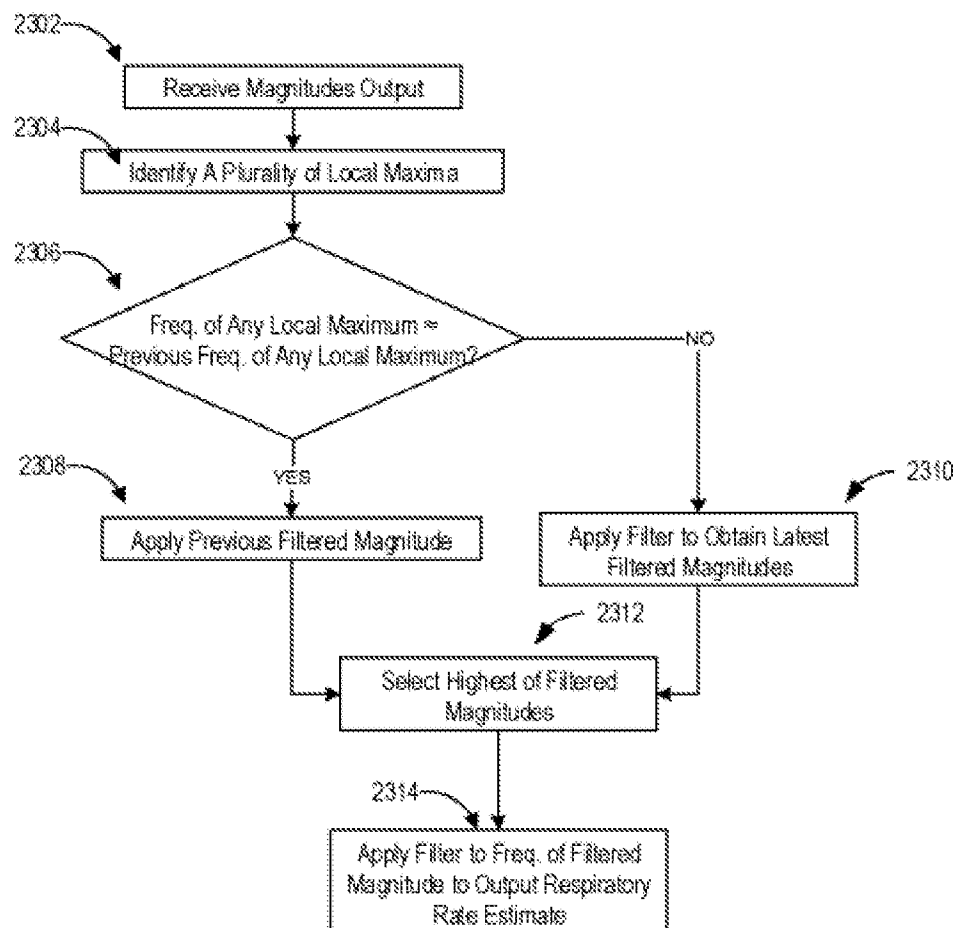
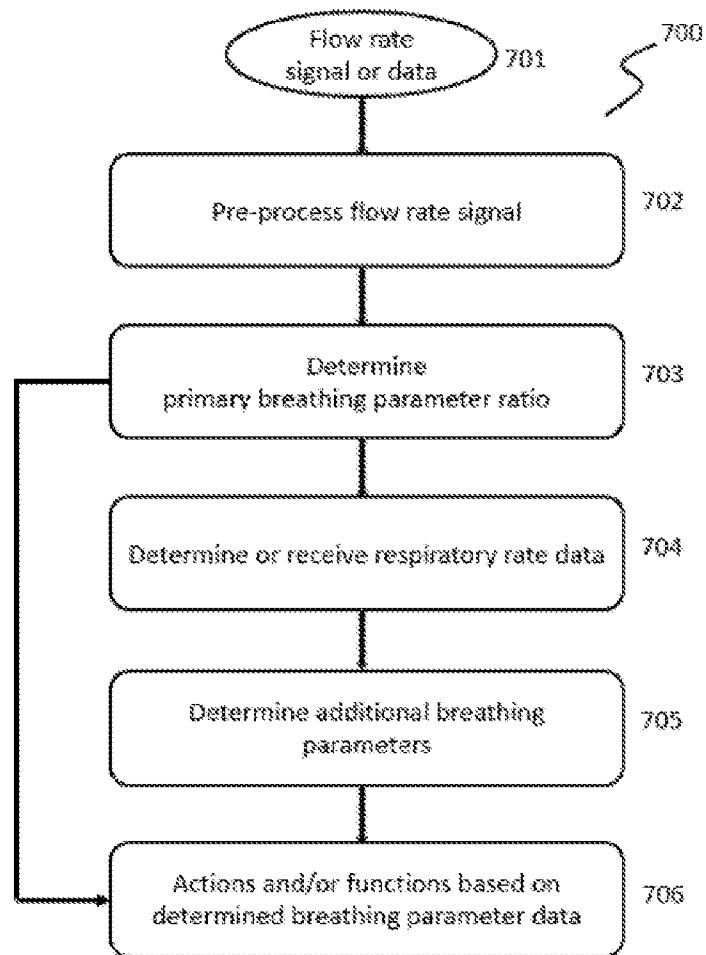
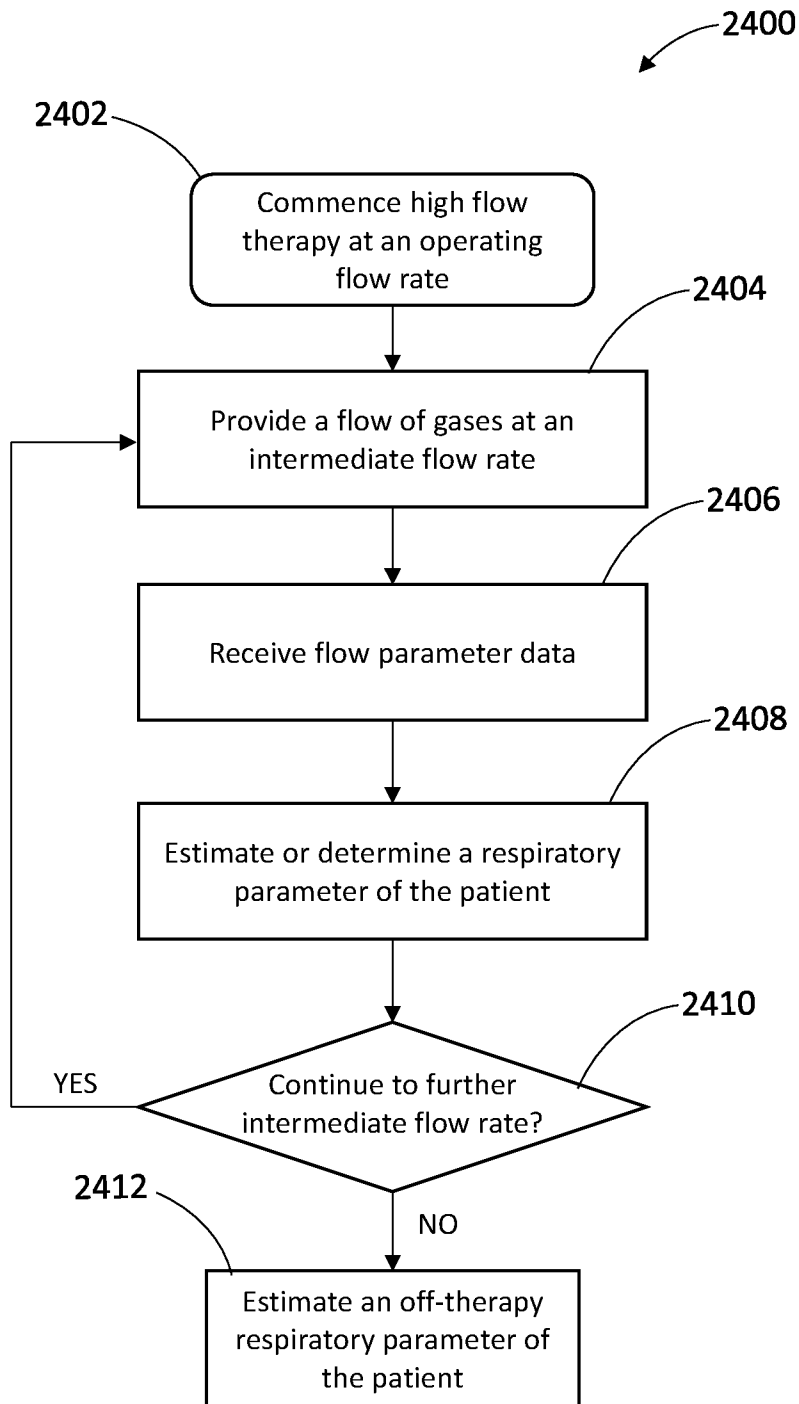


FIG. 5

**FIG. 6**

**FIG. 7**

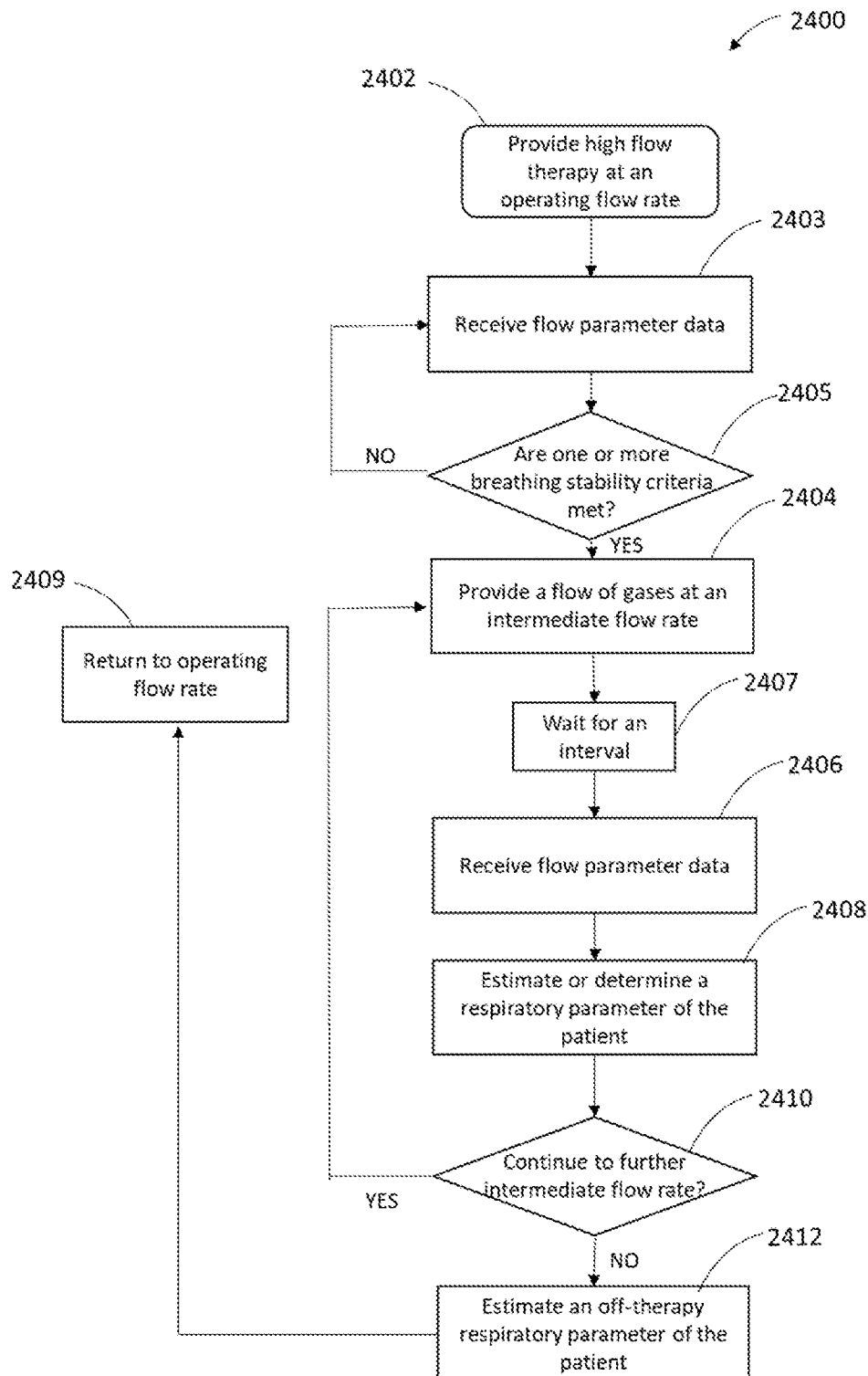
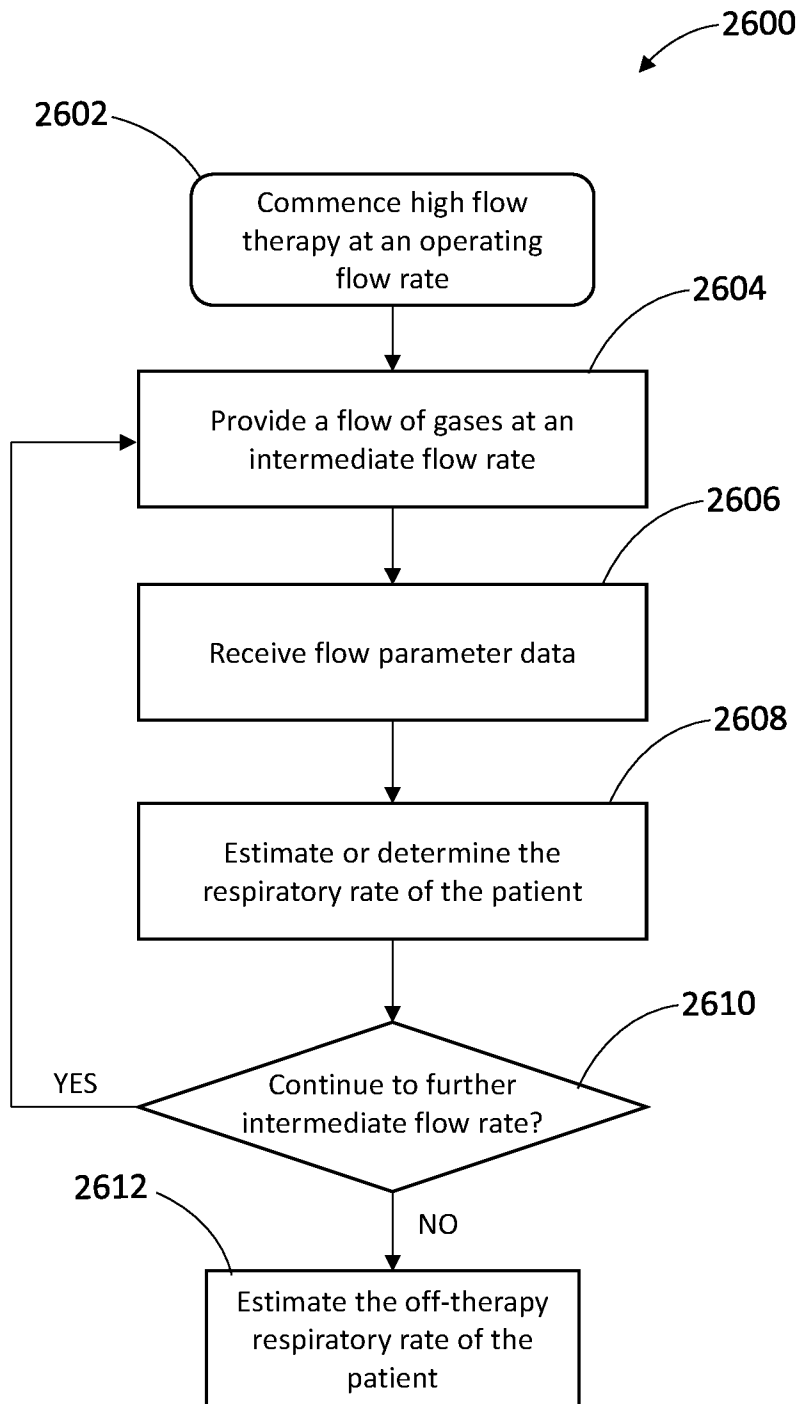


FIG. 8

**FIG. 9**

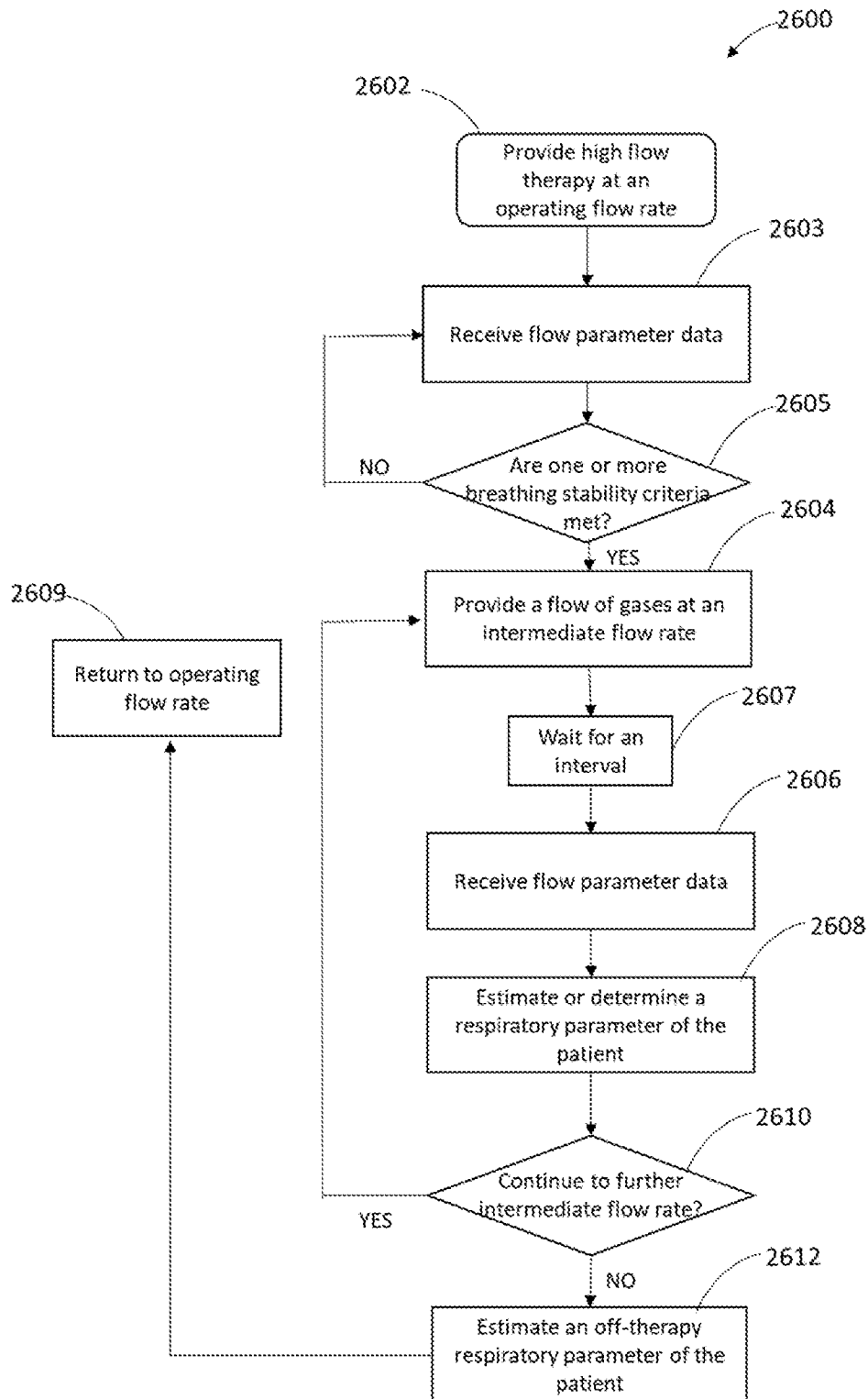


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2024/055238

A. CLASSIFICATION OF SUBJECT MATTER

**A61M 16/00 (2006.01) A61B 5/00 (2006.01) A61B 5/08 (2006.01) A61B 5/087 (2006.01) A61M 16/06 (2006.01)
A61M 16/10 (2006.01)**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PATENW is a cluster of databases EPODOC and full text English language clusters **PATENW: IPC/CPC:** A61M16/0069, A61M16/026, A61M2016/0027, A61M2016/0036, A61M16/0666, A61M2205/3334, A61M2205/35, A61M2205/50, A61M2230/005, A61M2230/42, A61M16/0003, A61M16/0051, A61M16/1005, A61M16/00, A61M16/0066/LOW, A61M16/0003/LOW, A61B5/0816, A61B5/082, A61B5/083/LOW, A61B5/087/LOW, A61M2205/33/LOW, A61B5/7275, A61B5/4836, A61B5/4833, A61B5/4843, A61B5/4848, G16H20/40, A61B5/74/LOW **KEYWORDS:** respiratory parameter, flow generator, flow rate, pressure, respiratory rate, inspiratory- expiratory ratio, frequency analysis, therapeutic flow rate, oxygen concentration, model, linear equation, intermediate flow rates, estimate, controlling the flow generator, transmitting data to external device, thresholds, parameters, alert, alarm, notification, FiO2, oxygen percentage, sensors, controller, non-sealed therapy system, nasal high flow therapy, calculate, determine, respiratory therapy, CPAP, ventilator, blower, estimate, predict, off-therapy parameter, local maxima, peak, adjust, change, control, alter, increase, ramp, gradual, hold, pause, stabilise, monitor, measure, calculate, linear model, limit and the like. **Google Patents, Google Scholar, Medline, Inspec and Espacenet:** Keywords: as above. **Applicant and Inventor** searched in internal database provided by IP Australia.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

☒ Further documents are listed in the continuation of Box C

☒ See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"D" document cited by the applicant in the international application	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
22 August 2024

Date of mailing of the international search report
22 August 2024

Name and mailing address of the ISA/AU

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INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. PCT/IB2024/055238
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2022167960 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 11 August 2022 Paragraphs 0004, 0006, 0007, 0009, 0012, 0046, 0081, 0082, 0083, 0084, 0087, 0093, 0103, 0128, 0136, 0147, 0148, 0158, 0159, 0171, 0172, 0173, 0209, Fig 1A.	1-118
X	WO 2019102384 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 31 May 2019 Paragraphs 0010, 0014, 0025, 0026, 0018, 0039, 0062-0065, 0163, 0183, 0291, 0296, 0317, 0318, 0320, 0322, 0337, 0371, 0373, 0416, 0432, Fig 1.	1-118
A	US 2016193438 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 07 July 2016 complete document	1-118
A	WO 2019102384 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 31 May 2019 complete document	1-118
A	WO 2016068725 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 06 May 2016 complete document	1-118
A	US 7845350 B1 (CLEVELAND MEDICAL DEVICES INC) 07 December 2010 complete document	1-118
A	WO 2022070022 A1 (RESMED SENSOR TECHNOLOGIES LIMITED) 07 April 2022 complete document	1-118
A	WO 2022167982 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 11 August 2022 complete document	1-118
A	WO 2017059530 A1 (UNIVERSITÉ LAVAL et al) 13 April 2017 complete document	1-118
Form PCT/ISA/210 (fifth sheet) (July 2019)		

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box for Details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Supplemental Box

Continuation of: Box III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- **Claims 1-106** are directed to a method of estimating an off-therapy respiratory parameter of a patient during therapy. The feature of *estimating or determining a respiratory parameter based on sensor data to estimate an off-therapy parameter* is specific to this group of claims.
- **Claims 107-118** are directed to a respiratory therapy apparatus. The features of *determining or receiving an indication of an off-therapy parameter and using this to adjust the flow rate of the therapy* are specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is a *respiratory therapy comprising a flow generator to generate a plurality of flow rates and at least one sensor to determine flow parameter data*. However this feature does not make a contribution over the prior art because it is disclosed in:

WO2022167960A1 (Fisher & Paykel Healthcare Limited) 11 Aug 2022

Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a posteriori*.

INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/IB2024/055238	
This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.			
Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	Publication Date	Publication Number	Publication Date
WO 2022167960 A1	11 August 2022	WO 2022167960 A1	11 Aug 2022
		AU 2022217520 A1	17 Aug 2023
		CN 117295449 A	26 Dec 2023
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		EP 4287942 A1	13 Dec 2023
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		CN 111432866 B	19 Mar 2024
		CN 118142041 A	07 Jun 2024
		CN 118203728 A	18 Jun 2024
		CN 118203729 A	18 Jun 2024
		CN 118286549 A	05 Jul 2024
		CN 118454034 A	09 Aug 2024
		EP 3713629 A1	30 Sep 2020
		EP 3713629 B1	10 Jul 2024
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		US 2021113796 A1	22 Apr 2021
		US 11883594 B2	30 Jan 2024
		US 2024115824 A1	11 Apr 2024
US 2016193438 A1	07 July 2016	US 2016193438 A1	07 Jul 2016
		US 11464928 B2	11 Oct 2022
		AU 2014316671 A1	24 Mar 2016
		AU 2014316671 A2	11 May 2017
		AU 2014316671 B2	19 Dec 2019
		AU 2019275640 A1	02 Jan 2020
		AU 2021203998 A1	08 Jul 2021
		AU 2023202478 A1	11 May 2023
		EP 3030302 A1	15 Jun 2016
		EP 3030302 B1	22 Feb 2023
		EP 4205787 A1	05 Jul 2023
		US 2016030690 A1	04 Feb 2016
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INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/IB2024/055238	
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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	Publication Date	Publication Number	Publication Date
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		US 2019336712 A1	07 Nov 2019
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		US 2017087316 A1	30 Mar 2017
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		US 11883594 B2	30 Jan 2024
		US 2024115824 A1	11 Apr 2024
		WO 2016068725 A1	06 May 2016
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		AU 2024200467 A1	15 Feb 2024
		EP 3212263 A1	06 Sep 2017
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US 10722670 B2	28 Jul 2020		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

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INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/IB2024/055238	
This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.			
Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	Publication Date	Publication Number	Publication Date
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		US 11771858 B2	03 Oct 2023
		US 2024091475 A1	21 Mar 2024
WO 2022070022 A1	07 April 2022	US 7845350 B1	07 Dec 2010
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		CA 3000522 A1	13 Apr 2017
		EP 3359237 A1	15 Aug 2018
		US 2018280645 A1	04 Oct 2018
		US 11065408 B2	20 Jul 2021
End of Annex			
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001. Form PCT/ISA/210 (Family Annex)(July 2019)			