



(51) International Patent Classification:

A61M 16/00 (2006.01) A61M 16/20 (2006.01)
A61B 5/00 (2006.01)

(21) International Application Number:

PCT/EP2022/054146

(22) International Filing Date:

18 February 2022 (18.02.2022)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/151,823 22 February 2021 (22.02.2021) US

(71) Applicant: **KONINKLIJKE PHILIPS N.V.** [NL/NL]; High Tech Campus 52, 5656 AG Eindhoven (NL).

(72) Inventors: **MORGAN, Stephan Daniel**; c/o Philips International B.V. Intellectual Property and Standards, High Tech Campus 52, 5656 AG Eindhoven (NL). **FAZIO, Adrienne K**; c/o Philips International B.V. Intellectual Property and Standards, High Tech Campus 52, 5656 AG Eindhoven (NL). **CATALANO, Thomas**; c/o Philips International B.V. Intellectual Property and Standards, High Tech Campus 52, 5656 AG Eindhoven (NL). **WINSKI, Jeffrey Ronald**; c/o Philips International B.V. Intellectual Property

and Standards, High Tech Campus 52, 5656 AG Eindhoven (NL).

(74) Agent: **PHILIPS INTELLECTUAL PROPERTY & STANDARDS**; High Tech Campus 52, 5656 AG Eindhoven (NL).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

(54) Title: METHOD FOR PROVIDING COMFORT FEATURE IN A PRESSURE SUPPORT DEVICE AND PRESSURE SUPPORT DEVICE INCLUDING SAME

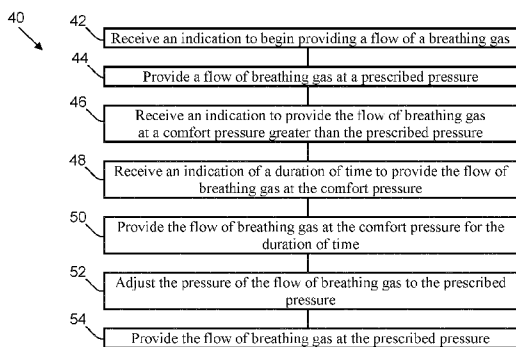


FIG. 3

(57) Abstract: A method and apparatus (40, 60) of providing a pressure support therapy to a patient via a PAP device, the method comprising: providing (44, 64) a flow of a breathing gas at a comfort pressure for communication to an airway of the patient for a predetermined period of time; and adjusting (52, 66) the pressure of the flow of the breathing gas from the comfort pressure to a prescribed pressure, wherein the comfort pressure is greater than the prescribed pressure.

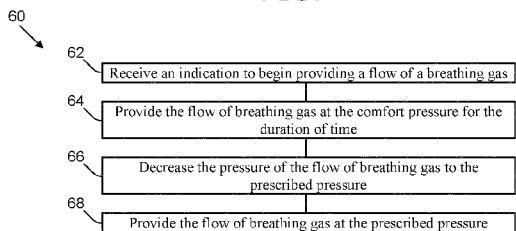


FIG. 4

WO 2022/175487 A1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

METHOD FOR PROVIDING COMFORT FEATURE IN A PRESSURE SUPPORT DEVICE AND PRESSURE SUPPORT DEVICE INCLUDING SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

[01] The present invention pertains to methods of providing a pressure support therapy to a patient. The present invention also pertains to pressure support devices employing such methods.

2. Description of the Related Art

[02] Many individuals suffer from disordered breathing during sleep. Sleep apnea is a common example of such sleep disordered breathing suffered by millions of people throughout the world. One type of sleep apnea is obstructive sleep apnea (OSA), which is a condition in which sleep is repeatedly interrupted by an inability to breathe due to an obstruction of the airway; typically the upper airway or pharyngeal area. Obstruction of the airway is generally believed to be due, at least in part, to a general relaxation of the muscles which stabilize the upper airway segment, thereby allowing the tissues to collapse the airway. Another type of sleep apnea syndrome is a central apnea, which is a cessation of respiration due to the absence of respiratory signals from the brain's respiratory center. An apnea condition, whether OSA, central, or mixed, which is a combination of OSA and central, is defined as the complete or near cessation of breathing, for example a 90% or greater reduction in peak respiratory air-flow.

[03] Those afflicted with sleep apnea experience sleep fragmentation and complete or nearly complete cessation of ventilation intermittently during sleep with potentially severe degrees of oxyhemoglobin desaturation. These symptoms may be translated clinically into extreme daytime sleepiness, cardiac arrhythmias, pulmonary-artery hypertension, congestive heart failure and/or cognitive dysfunction. Other consequences of sleep apnea include right ventricular dysfunction, carbon dioxide retention during wakefulness, as well as during sleep, and continuous reduced arterial oxygen tension. Sleep apnea sufferers may be at risk for excessive mortality from these

factors as well as by an elevated risk for accidents while driving and/or operating potentially dangerous equipment.

[04] Even if a patient does not suffer from a complete or nearly complete obstruction of the airway, it is also known that adverse effects, such as arousals from sleep, can occur where there is only a partial obstruction of the airway. Partial obstruction of the airway typically results in shallow breathing referred to as a hypopnea. A hypopnea is typically defined as a 50% or greater reduction in the peak respiratory air-flow. Other types of sleep disordered breathing include, without limitation, upper airway resistance syndrome (UARS) and vibration of the airway, such as vibration of the pharyngeal wall, commonly referred to as snoring. Thus, in diagnosing a patient with a breathing disorder, such as OSA, central apneas, or UARS, it is important to detect accurately the occurrence of apneas and hypopneas of the patient.

[05] It is well known to treat sleep disordered breathing by applying a positive airway pressure (PAP) to the patient's airway using an airway pressure support system that typically includes a mask, a pressure generating device, and a conduit to deliver positive pressure breathing gas from the pressure generating device to the patient through the mask. This positive pressure effectively "splints" the airway, thereby maintaining an open passage to the lungs. In one type of PAP therapy, known as continuous positive airway pressure (CPAP), the pressure of gas delivered to the patient is constant throughout the patient's breathing cycle. It is also known to provide a positive pressure therapy in which the pressure of gas delivered to the patient varies with the patient's breathing cycle, or varies with the patient's effort, to increase the comfort to the patient. This pressure support technique is referred to as bi-level pressure support, in which the inspiratory positive airway pressure (IPAP) delivered to the patient is higher than the expiratory positive airway pressure (EPAP).

[06] Today in CPAP delivery to patients, prescriptions are written as such that a patient is prescribed a fixed CPAP pressure (constant delivery of a therapeutic pressure) or an Auto CPAP with additional prescribed minimum and maximum pressures so that an auto algorithm can operate within the bounds of the set pressure range. It is not uncommon for patients, especially those new to CPAP therapy, to feel discomfort with

their prescribed pressure when falling asleep. Often times this pressure is too high. To address this discomfort, CPAP providers offer a feature called Ramp or Fixed Ramp. When activated, such feature allows patients to drop their delivered pressure down to 4cmH₂O up to whatever their prescribed CPAP pressure or prescribed Auto minimum pressure is. The pressure delivered starts at the set Ramp pressure and begins to “ramp” up and increase (linearly) the delivered pressure for a set period of time until the prescribed pressure is reached. Once the set period of time has concluded, the device delivers the fixed pressure (CPAP) or goes back into Auto mode and titrates to the appropriate pressure level.

[07] In devices such as the Philips DreamStation that also offer SMART Ramp the initial behavior is the same as explained above for Ramp. However, the device uses event detection during the Ramp period to identify if a patient has had an event requiring more pressure than what is being delivered during Ramp. In such instance, the device’s auto algorithm kicks in and increases delivered pressure as needed so as not to allow the patient to experience unnecessary events.

[08] Patients generally are allowed to set their own Ramp pressure and Ramp time (usually between 5 and 45 minutes in 5 minute increments). In a CPAP device manufactured and distributed by Philips, there is a dedicated Ramp button that allows the patient to tap each night to activate Ramp, thus dropping the delivered pressure to the lower Ramp pressure. In a CPAP device manufactured and distributed by ResMed, the Ramp pressure is allowed to be set so that once set and therapy is turned off, the device will deliver that Ramp starting pressure when therapy is turned back ON, thus eliminating any need to tap a button to start Ramp.

[09] In the aforementioned Ramp features the bounds of Ramp pressure available to patients are limited, i.e., from 4cmH₂O to fixed CPAP pressure or min Auto pressure. For example, if a patient is prescribed an Auto device set from 5cmH₂O (min) to 20 cmH₂O (max), the possible Ramp pressures the patient can select from are only 4cmH₂O or 4.5cmH₂O. The 5-20cmH₂O Auto prescription is the most commonly prescribed. In this case the device will start delivering therapy at a pressure of 5cmH₂O if Ramp is OFF or a pressure of say 4cmH₂O if Ramp is ON. This might be satisfactory

if 5cmH₂O was too high for a patient and felt uncomfortable. However, if a patient felt air starved or felt like they were suffocating at 5cmH₂O, there is no option to increase the pressure.

[10] In a Philips assessment of patient therapy trends, we have seen that 25% of the time patients are getting an adjustment to their prescribed minimum pressure (when using an Auto mode) in the first 90 days of therapy. Over 85% of these adjustments result in an increase of the minimum prescribed pressure. This suggests that patients are either uncomfortable at lower pressure settings or that a physician may feel like there is a more optimal minimum pressure for treating events.

[11] The current limitations of devices do not allow patients to select an actual starting pressure that is most comfortable for them to fall asleep to. If the pressure is too low and they feel air starved, they are unable to fall asleep, resulting in no therapy and a possible restless night. Accordingly, there is room for improvement in devices used in providing pressure support therapy and the methods employed thereby.

SUMMARY OF THE INVENTION

[12] Embodiments of the present invention provide improved methods and devices for providing pressure support therapy to patients. As one aspect of the invention, a method of providing a pressure support therapy to a patient via a PAP device is provided. The method comprises: providing a flow of a breathing gas at a comfort pressure for communication to an airway of the patient for a predetermined period of time; and adjusting the pressure of the flow of the breathing gas from the comfort pressure to a prescribed pressure, wherein the comfort pressure is greater than the prescribed pressure.

[13] The method may further comprise receiving an indication of the comfort pressure prior to providing the flow of the breathing gas at the comfort pressure.

[14] The method may further comprise providing a flow of the breathing gas at the prescribed pressure prior to providing the flow of the breathing gas at the comfort pressure.

[15] Providing the flow of the breathing gas at the comfort pressure may comprise providing the flow of breathing gas at a first comfort pressure and adjusting the

flow of breathing gas being provided to a second comfort pressure responsive to receiving an indication from the patient of a different comfort pressure.

- [16] Adjusting the flow of breathing gas from the comfort pressure to the prescribed pressure may comprise reducing the pressure of the flow of the breathing gas over a period of time. The period of time may be in the range of 1 to 5 minutes.
- [17] The flow of the breathing gas may be provided at the comfort pressure upon commencement of a pressure support therapy.
- [18] The comfort pressure may be in the range of from 4 cmH₂O to 10 cmH₂O.
- [19] The method may further comprise providing an indication to the patient of the comfort pressure of the breathing gas being provided.
- [20] As another aspect of the present invention, a pressure support device for providing pressure support therapy to a patient is provided. The pressure support device comprises: an airflow generator structured to generate pressure to provide pressure compensation to the patient via a patient circuit; and a processing unit programmed to: cause the airflow generator to provide a flow of a breathing gas at a comfort pressure for communication to an airway of the patient for a predetermined period of time; and adjust the pressure of the flow of the breathing gas being provided by the airflow generator to decrease from the comfort pressure to a prescribed pressure.
- [21] The processing unit may be further programmed to receive an indication of the comfort pressure prior to causing the airflow generator to provide the flow of the breathing gas at the comfort pressure.
- [22] The processing unit may be further programmed to cause the airflow generator to provide a flow of the breathing gas at the prescribed pressure prior to providing the flow of the breathing gas at the comfort pressure.
- [23] The processing unit may be programmed to cause the airflow generator to provide the flow of breathing gas at a first comfort pressure and adjust the flow of breathing gas being provided to a second comfort pressure responsive to receiving an indication from the patient of a different comfort pressure.
- [24] As yet another aspect of the present invention, a tangible machine readable medium is provided. The tangible machine readable medium comprises instructions for

causing an airflow generator to provide a flow of a breathing gas at a comfort pressure for communication to an airway of a patient for a predetermined period of time; and to adjust the pressure of the flow of the breathing gas being provided by the airflow generator to decrease from the comfort pressure to a prescribed pressure.

[25] The processing unit may be programmed to cause the airflow generator to provide the flow of breathing gas at a first comfort pressure and adjust the flow of breathing gas being provided to a second comfort pressure responsive to receiving an indication from the patient of a different comfort pressure.

[26] These and other objects, features, and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[27] FIG. 1 is a schematic diagram of a pressure support system adapted to provide a regimen of respiratory therapy to a patient according to one example embodiment of the present invention;

[28] FIG. 2 is a schematic diagram of a processing unit according to one example embodiment of the present invention;

[29] FIG. 3 is a flowchart of a method of providing a pressure support therapy to a patient according to one example embodiment of the present invention that can be carried out using a pressure support system such as shown in FIG. 1; and

[30] FIG. 4 is a flowchart of another method of providing a pressure support therapy to a patient according to another example embodiment of the present invention that can be carried out using a pressure support system such as shown in FIG. 1.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

- [31] As used herein, the singular form of “a”, “an”, and “the” include plural references unless the context clearly dictates otherwise. As used herein, the statement that two or more parts or components are “coupled” shall mean that the parts are joined or operate together either directly or indirectly, i.e., through one or more intermediate parts or components, so long as a link occurs. As used herein, “directly coupled” means that two elements are directly in contact with each other. As employed herein, the term “number” shall mean one or an integer greater than one (i.e., a plurality).
- [32] Directional phrases used herein, such as, for example and without limitation, top, bottom, left, right, upper, lower, front, back, and derivatives thereof, relate to the orientation of the elements shown in the drawings and are not limiting upon the claims unless expressly recited therein.
- [33] Referring to FIG. 1, a schematic diagram of an airway pressure support system 2 according to one particular, non-limiting exemplary embodiment of the present invention in which methods in accordance with example embodiments of the present invention may be implemented is shown. Airway pressure support system 2 includes a pressure support device 4 which houses a gas flow generator 6, such as a blower used in a conventional CPAP or bi-level pressure support device. Gas flow generator 6 receives breathing gas, generally indicated by arrow C, from the ambient atmosphere through an air inlet 8 provided as part of pressure support device 4, and generates a flow of breathing gas therefrom for delivery to an airway of a patient 10 at relatively higher and lower pressures, i.e., generally equal to or above ambient atmospheric pressure. In the example embodiment shown in FIG. 1, gas flow generator 6 is capable of providing a flow of breathing gas ranging in pressure from 3-30 cmH₂O, but typically operates at prescription pressures from 4-20 cmH₂O. The pressurized flow of breathing gas from gas flow generator 6, generally indicated by arrow D, is delivered via a delivery conduit 12 to a breathing mask or patient interface 14 of any known construction, which is typically worn by, or otherwise attached to, patient 10 in order to communicate flow D of breathing gas to the airway of patient 10. Delivery conduit 12 and patient interface device 14 are typically collectively referred to as a patient circuit.

[34] Pressure support system 2 shown in FIG. 1 is what is known as a single-limb system, meaning that the patient circuit includes only delivery conduit 12 connecting patient 10 to pressure support system 2. As such, an exhaust vent 16 is provided in delivery conduit 12 for venting exhaled gases from the system as indicated by arrow E. It should be noted that exhaust vent 16 can be provided at other locations in addition to, or instead of in delivery conduit 12, such as in patient interface device 14. It should also be understood that exhaust vent 16 can have a wide variety of configurations depending on the desired manner in which gas is to be vented from pressure support system 2.

[35] The present invention also contemplates that pressure support system 2 can be a two-limb system, having a delivery conduit and an exhaust conduit connected to patient 10. In a two-limb system (also referred to as a dual-limb system), the exhaust conduit carries exhaust gas from patient 10 and includes an exhaust valve at the end distal from patient 10. The exhaust valve in such an embodiment is typically actively controlled to maintain a desired level or pressure in the system, which is commonly known as positive end expiratory pressure (PEEP).

[36] Furthermore, in the example embodiment shown in FIG. 1, patient interface 14 is a nasal/oral mask. It is to be understood, however, that patient interface 14 can include a nasal mask, nasal pillows, a tracheal tube, an endotracheal tube, or any other device that provides a suitable gas flow communicating function. Also, for purposes of the present invention, the phrase “patient interface” can include delivery conduit 12 and any other structures that couple the source of pressurized breathing gas to patient 10.

[37] In the example embodiment shown in FIG. 1, pressure support system 2 includes a pressure controller in the form of a valve 18 provided in an internal delivery conduit 20 provided in a housing (not numbered) of pressure support device 4. Valve 18 controls the pressure of flow D of breathing gas from gas flow generator 6 that is delivered to patient 10. For present purposes, gas flow generator 6 and valve 18 are collectively referred to as a pressure generating system because they act in concert to control the pressure and/or flow of gas delivered to patient 10. However, it should be

apparent that other techniques for controlling the pressure of the gas delivered to patient 10, such as varying the blower speed of gas flow generator 6, either alone or in combination with a pressure control valve, are contemplated by the present invention. Thus, valve 18 is optional depending on the technique used to control the pressure of the flow of breathing gas delivered to patient 10. If valve 18 is eliminated, the pressure generating system corresponds to gas flow generator 6 alone, and the pressure of gas in the patient circuit is controlled, for example, by controlling the motor speed of gas flow generator 6.

[38] Pressure support system 2 further includes a flow sensor 22 that measures the flow of the breathing gas within delivery conduit 20 and delivery conduit 12. In the particular embodiment shown in FIG. 1, flow sensor 22 is interposed in line with delivery conduits 20 and 12, most preferably downstream of valve 18. Pressure support system 2 additionally includes a pressure sensor 24 that detects the pressure of the pressurized fluid in delivery conduit 20. While the points at which the flow is measured by flow sensor 22 and the pressure is measured by pressure sensor 24 are illustrated as being within pressure support device 4, it is to be understood that the location at which the actual flow and pressure measurements are taken may be anywhere along delivery conduits 20 or 12. The flow of breathing gas measured by flow sensor 22 and the pressure detected by pressure sensor 24 are provided to a processing unit 26 to determine the flow D of gas to patient 10.

[39] Techniques for calculating the flow D of gas to patient 10 are well known, and take into consideration the pressure drop of the patient circuit, known leaks from the system, i.e., the intentional exhausting of gas from the circuit as indicated by arrow E in FIG. 1, and unknown leaks from the system, such as leaks at the mask/patient interface. The present invention contemplates using any known or hereafter developed technique for calculating leak flow, and using this determination in calculating flow D to patient 10 using measured flow and pressure. Examples of such techniques are taught by U.S. Patent Nos. 5,148,802; 5,313,937; 5,433,193; 5,632,269; 5,803,065; 6,029,664; 6,539,940; 6,626,175; and 7,011,091, the contents of each of which are incorporated by reference herein.

- [40] Of course, other techniques for measuring the respiratory flow of patient 10 are contemplated by the present invention, such as, without limitation, measuring the flow directly at patient 10 or at other locations along delivery conduit 12, measuring patient flow based on the operation of gas flow generator 6, and measuring patient flow using a flow sensor upstream of valve 18.
- [41] In some non-limiting embodiments of the disclosed concept, pressure support system 2 also includes a proximal pressure sensor 28 that is in fluid communication with a point along delivery conduit 12. For example, without limitation, proximal pressure sensor 28 may be in fluid communication with a point on delivery conduit 12 near patient interface device 14 via a probe connected between proximal pressure sensor 28 and the point on delivery conduit 12. Proximal pressure sensor 28 facilitates measuring pressure proximate the point on delivery conduit 12 and provides the measured proximal pressure to processing unit 24. It will be appreciated that in some exemplary embodiments, proximal pressure sensor 28 may be omitted.
- [42] While the flow sensor 22, pressure sensor 24, and proximal pressure sensor 28 have been shown in conjunction with the pressure support system 2 illustrated in FIG. 1, it will be appreciated by those having ordinary skill in the art that other types of sensors may also be employed in conjunction with pressure support system 2 without departing from the scope of the disclosed concept.
- [43] Referring now to FIG. 2 in addition to FIG. 1, processing unit 26 includes a processor 30, a memory 32, and a communication unit 34. Processor 30 may form all or part of a processing portion which may be, for example, a microprocessor, a microcontroller any other suitable processing device. Memory 32 may form all or part of a memory portion that may be internal to the processing portion or operatively coupled to the processing portion and provide a storage medium for data and software executable by the processing portion for implementing functionality of processing unit 26 and controlling the operation of pressure support system 2. Memory 32 can be any of one or more of a variety of types of internal and/or external storage media such as, without limitation, RAM, ROM, EPROM(s), EEPROM(s), FLASH, and the like that provide a storage register, i.e., a machine readable medium, for data storage such as in the fashion

of an internal storage area of a computer, and can be volatile memory or nonvolatile memory. Processing unit 26 is structured to receive outputs of one or more sensors structured to gather data related to effectiveness of the pressure support therapy and to provide control outputs to one or more elements of pressure support system 2. An example of such sensors is flow sensor 22 and pressure sensor 24, however, other types of sensors may also gather data related to effectiveness of the pressure support therapy and be employed with processing unit 26. Processing unit 26 is also structured to analyze outputs of the sensors while pressure support therapy is provided to the patient to determine patient airflow and pressure waveforms in the patient circuit.

[44] An input/output arrangement 36 is provided for setting various parameters used by airway pressure support system 2, as well as for displaying and outputting information and data to a user, such as a patient, clinician or caregiver. Input/output arrangement 36 may include one or more of: a display, electromechanical buttons, a touchscreen, or any other suitable arrangement for providing input to, or providing output from, processing unit 26 and may be included in/on the housing of pressure support device 4 or separate therefrom and in wireless communication (e.g., via Bluetooth® or other suitable arrangement) with processing unit 26.

[45] It will be appreciated that pressure support device 4 may include additional components that are not illustrated in the schematic diagram of FIG. 1. For example, without limitation, pressure support device 4 may include a filter to filter breathing gas provided to patient 10 and/or a humidifier to humidify breathing gas provided to patient 10.

[46] In the illustrated, non-limiting exemplary embodiment of the present invention, airway pressure support system 2 essentially functions as a CPAP pressure support system and pressure support device 4 provides functions of a CPAP base unit. Pressure support system 2, therefore, includes all of the capabilities necessary in such systems in order to provide appropriate CPAP pressure levels to patient 10. This includes receiving the necessary parameters, via input commands, signals, instructions or other information, for providing appropriate CPAP pressure, such as maximum and minimum CPAP pressure settings. It should be understood that this is meant to be exemplary only,

and that other pressure support methodologies, including, but not limited to, BiPAP AutoSV, AVAPS, Auto CPAP, and BiPAP Auto, are within the scope of the present invention.

[47] Communication unit 34 may provide for communication between processing unit 26 and other components of pressure support device 4, components of the patient circuit, or other external devices via the internet, cellular, WiFi, wired telephone line, or any other suitable means. For example, without limitation, communication unit 34 may facilitate communication with various sensors such as flow control sensor 22. Communication unit 34 may also facilitate communication with external devices. For example, without limitation, communication unit 34 may facilitate communication with electronic devices such as a phone, tablet, computer, or other devices whether local or distant, directly or via a network. Communication facilitated by communication unit 34 may allow processing unit 26 to send and/or receive data from the component or device it communicates with.

[48] Having thus described the basic arrangement and components of pressure support system 2 and pressure support device 4 thereof, a method 40 in accordance with one example embodiment of the present invention which can be carried out using pressure support device 4 will now be described in conjunction with the flow chart of FIG. 3. Such method is an example of what would typically be carried out when a patient first uses a pressure support device 4 in accordance with an embodiment of the present invention. As shown at 42, method 40 begins when an indication to begin providing a flow of a breathing gas is received by processing unit 26. Such indication may be provided by a user (i.e., a patient): powering up pressure support device 4 via a power button or other suitable arrangement, by selecting a “start” function such as a via input/output arrangement 36, or via any other suitable arrangement. After such indication is received, processing unit 26 causes pressure support device 4 to begin to provide flow D of breathing gas at a pressure prescribed to the patient by a caregiver (i.e., a prescribed pressure), such as shown at 44. If/when, such as shown at 46, an indication to provide the flow of breathing gas at a comfort pressure other than the prescribed pressure is received by processing unit 26 (e.g., greater or lesser than the prescribed pressure),

pressure support device then provides the flow of breathing gas at the comfort pressure, such as shown at 50. Such indication may be provided by a user pressing a button or selecting an icon on a touchscreen or via any other suitable arrangement.

[49] The comfort pressure may be a preset pressure set by a manufacturer, caregiver or by the user, or may be a pressure selected by the user (e.g., via input/output arrangement 36 after turning on pressure support device 4. Such selection of the comfort pressure may be made while pressure support device 4 is providing flow D of breathing gas to the patient, thus allowing for the patient to actively feel the selected comfort pressure and decide upon the pressure that feels best to the patient. In one example embodiment of the present invention, the user/patient is provided with selectable options for setting the comfort pressure, e.g., low, medium, high, max wherein each setting corresponds to a particular pressure (e.g., low – 4 cmH₂O, med – 6 cmH₂O, high - 8 cm H₂O, max – 10 cm H₂O). In other example embodiments of the present invention, the user is able to select the comfort pressure with greater granularity either by increasing/decreasing a selected comfort pressure in 1 cmH₂O increments or by directly inputting a desired comfort pressure value from within an allowed range of comfort pressure values (e.g., 4-10 cmH₂O). In any case, such comfort pressure can exceed the prescribed pressure. In example embodiments, indications of the comfort pressure are provided to the user such as via input/output arrangement 36. Such indications may be in the form of numerical values, graphical displays or any other suitable indicators of the pressure or relative pressure level of the comfort pressure provided to the patient.

[50] Continuing to refer to FIG. 3, as further shown at 50, the flow of breathing gas is provided at the previously discussed comfort pressure for a duration of time. Ideally the duration of time at which the comfort pressure is provided should be slightly longer (e.g., without limitation, 5-10 minutes) than the time it takes the patient to fall asleep. The duration of time may be a preset duration previously set by a manufacturer, caregiver, or the patient themselves, or may be provided/selected (e.g., via input/output arrangement 36) by the patient immediately before or after starting the comfort function, such as shown at 48. In one example embodiment of the present invention, the user/patient is provided with selectable options for setting the duration, e.g., 15 min, 30

min, 45 min. In other example embodiments the user can adjust the duration with greater granularity either by increasing/decreasing the duration in predetermined increments (e.g., 1 min, 5 min) or by directly inputting a desired duration value from within an allowed range of duration values (e.g., without limitation, 10-60 min). Once the patient selects/sets the comfortable starting pressure, this pressure will be constantly delivered to the patient for the selected/set duration of time without increasing or ramping. However, in one example embodiment, if a patient falls asleep during the selected period and experiences an event, an auto algorithm will kick in (similar to SMART Ramp previously discussed) and will adjust and deliver pressure to the patient accordingly to what is needed in order to avoid additional events. Overall the general idea is that if the selected pressure is what is most comfortable for a patient, such pressure should be delivered to the patient until they fall asleep without making any changes that may cause the patient to not fall asleep. Once the duration of time has passed, the pressure of the provided flow of breathing gas is adjusted (i.e., increased or decreased) to the prescribed pressure(s) and pressure support device 4 will go on to deliver the appropriate therapy/prescribed pressures, such as shown at 52 and 54. In example embodiments of the present invention, such adjustment between the comfort pressure and the prescribed pressure may occur in a linear fashion over a period of time (e.g., a 1-5 minutes) or via any other suitable manner that minimizes potential disturbance of the patient.

[51] Another method 60 in accordance with another example embodiment of the present invention which can be carried out using pressure support device 4 will now be described in conjunction with the flow chart of FIG. 4. Such method is generally an example of what would typically be carried out when a patient uses a pressure support device 4 in accordance with an embodiment of the present invention subsequent to the usage described in conjunction with the method of FIG. 3. As shown at 62, method 60 begins when an indication to begin providing a flow of a breathing gas is received by processing unit 26. As previously discussed in conjunction with 42, such indication may be provided by a user (i.e., a patient): powering up pressure support device 4 via a power button or other suitable arrangement, by selecting a “start” function such as via input/output arrangement 36, or via any other suitable arrangement. As shown at 64,

after such indication is received at 62, processing unit 26 causes pressure support device 4 to begin to provide flow D of breathing gas at a comfort pressure, such as previously discussed, that is different than a prescribed pressure since such comfort pressure was previously indicated (such as via method 40) as being a desirable startup pressure at which to receive the flow of breathing gas until the patient falls asleep. As further shown at 64, the flow of breathing gas is provided constantly at the previously discussed comfort pressure for a duration of time, which may also be a duration previously selected by the patient such as previously described in conjunction with method 40 or at a new duration selected by the patient selected in a manner such as previously described. As discussed in regard to method 40, such comfort pressure will be constantly delivered to the patient for the selected/set duration of time without increasing or ramping. However, in one example embodiment, if a patient falls asleep during the selected period and experiences an event, an auto algorithm will kick in (like in SMART Ramp previously discussed) and will adjust and deliver pressure to the patient accordingly to what is needed in order to avoid additional events. Once again, the general idea is that if the selected pressure is what is most comfortable for a patient, such pressure should be delivered to the patient until they fall asleep without making any changes that may cause the patient to not fall asleep. Once the duration of time has passed, the pressure of the provided flow of breathing gas is adjusted to the prescribed pressure(s) and pressure support device 4 will go on to deliver the appropriate therapy/prescribed pressures, such as shown at 66 and 68. As previously discussed in regard to method 40, in example embodiments of the present invention, such adjustment (whether an increase or decrease in pressure) between the comfort pressure and the prescribed pressure may occur in a linear fashion over a period of time (e.g., a 1-5 minutes) or via any other suitable manner that minimizes potential disturbance of the patient.

[52] From the foregoing it is thus to be appreciated that embodiments of the present invention provide methods and arrangements that improve the comfort of patient receiving pressure support therapy as compared to conventional solutions.

[53] It is contemplated that aspects of the disclosed concept can be embodied as computer readable codes on a tangible computer readable recording medium. The

computer readable recording medium is any data storage device that can store data which can be thereafter read by a computer system. Examples of the computer readable recording medium include read-only memory (ROM), random-access memory (RAM), CD-ROMs, magnetic tapes, floppy disks, and optical data storage devices.

[54] Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

[55] In the claims, any reference signs placed between parentheses shall not be construed as limiting the claim. The word “comprising” or “including” does not exclude the presence of elements or steps other than those listed in a claim. In a device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The word “a” or “an” preceding an element does not exclude the presence of a plurality of such elements. In any device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The mere fact that certain elements are recited in mutually different dependent claims does not indicate that these elements cannot be used in combination.

What is Claimed is:

1. A method (40, 60) of providing a pressure support therapy to a patient via a PAP device, the method comprising:

providing (44, 64) a flow of a breathing gas at a comfort pressure for communication to an airway of the patient for a predetermined period of time; and
adjusting (52, 66) the pressure of the flow of the breathing gas from the comfort pressure to a prescribed pressure,
wherein the comfort pressure is greater than the prescribed pressure.

2. The method of claim 1, further comprising receiving an indication of the comfort pressure prior to providing the flow of the breathing gas at the comfort pressure.

3. The method of claim 1, further comprising providing a flow of the breathing gas at the prescribed pressure prior to providing the flow of the breathing gas at the comfort pressure.

4. The method of claim 1, wherein providing the flow of the breathing gas at the comfort pressure comprises providing the flow of breathing gas at a first comfort pressure and adjusting the flow of breathing gas being provided to a second comfort pressure responsive to receiving an indication from the patient of a different comfort pressure.

5. The method of claim 1, wherein adjusting the flow of breathing gas from the comfort pressure to the prescribed pressure comprises reducing the pressure of the flow of the breathing gas over a period of time.

6. The method of claim 5, wherein the period of time is in the range of 1 to 5 minutes.

7. The method of claim 1, wherein the flow of the breathing gas is provided at the comfort pressure upon commencement of a pressure support therapy.

8. The method of claim 1, wherein the comfort pressure is in the range of from 4 cmH₂O to 10 cmH₂O.

9. The method of claim 1, further comprising providing an indication to the patient of the comfort pressure of the breathing gas being provided.

10. A pressure support device (4) for providing pressure support therapy to a patient (10), the pressure support device comprising:

an airflow generator (6) structured to generate pressure to provide pressure compensation to the patient via a patient circuit (12, 14); and

a processing unit (26) programmed to:

cause the airflow generator to provide a flow of a breathing gas at a comfort pressure for communication to an airway of the patient for a predetermined period of time; and

adjusting the pressure of the flow of the breathing gas being provided by the airflow generator to decrease from the comfort pressure to a prescribed pressure.

11. The pressure support device of claim 10, wherein the processing unit is further programmed to receive an indication of the comfort pressure prior to causing the airflow generator to provide the flow of the breathing gas at the comfort pressure.

12. The pressure support device of claim 10, wherein the processing unit is further programmed to cause the airflow generator to provide a flow of the breathing gas at the prescribed pressure prior to providing the flow of the breathing gas at the comfort pressure.

13. The pressure support device of claim 12, wherein the processing unit is programmed to cause the airflow generator to provide the flow of breathing gas at a first comfort pressure and adjust the flow of breathing gas being provided to a second comfort pressure responsive to receiving an indication from the patient of a different comfort pressure.

14. A tangible machine readable medium comprising instructions for causing an airflow generator to provide a flow of a breathing gas at a comfort pressure for communication to an airway of a patient for a predetermined period of time; and
to adjust the pressure of the flow of the breathing gas being provided by the airflow generator to decrease from the comfort pressure to a prescribed pressure.

15. The tangible machine readable medium of claim 14, wherein the processing unit is programmed to cause the airflow generator to provide the flow of breathing gas at a first comfort pressure and adjust the flow of breathing gas being provided to a second comfort pressure responsive to receiving an indication from the patient of a different comfort pressure.

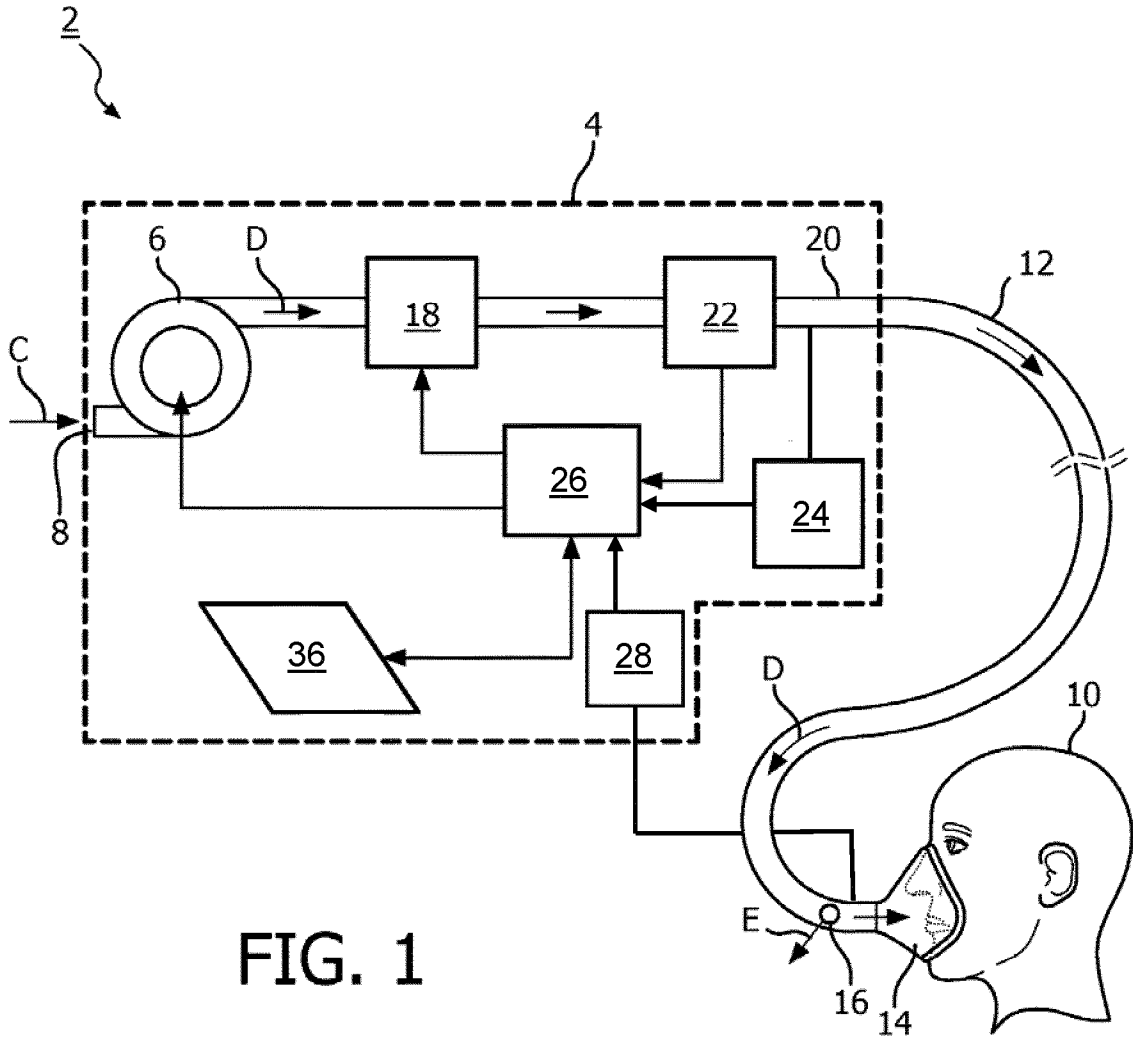


FIG. 1

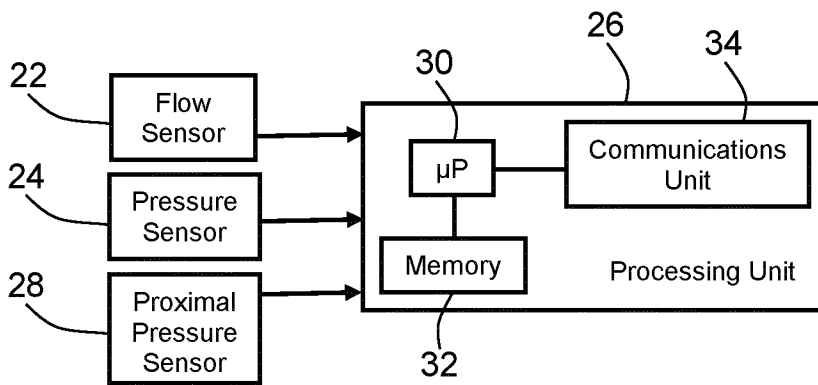


FIG. 2

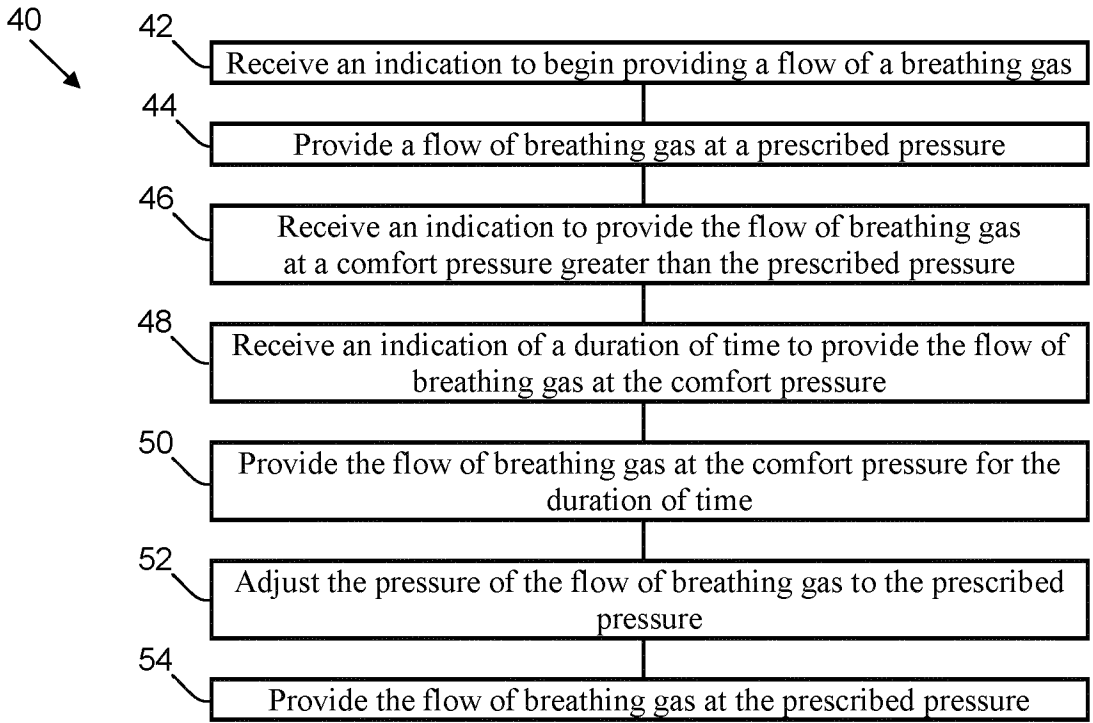


FIG. 3

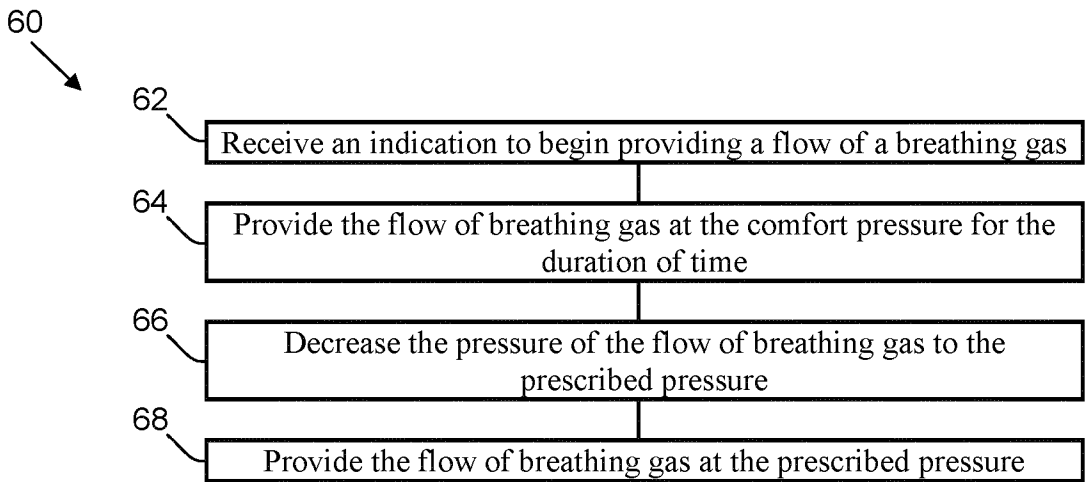


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2022/054146

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00 A61B5/00 A61M16/20
ADD.

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)
A61M A61B

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 9 731 089 B2 (BREATHE TECHNOLOGIES INC [US]) 15 August 2017 (2017-08-15) figures 7, 8 -----	1-15
A	US 9 937 309 B2 (DEVILBISS HEALTHCARE LLC [US]) 10 April 2018 (2018-04-10) figure 4 -----	1-15
A	WO 2019/063744 A1 (KONINKLIJKE PHILIPS NV [NL]) 4 April 2019 (2019-04-04) figure 1 -----	1-15
X	US 2006/249149 A1 (MEIER JOERG [DE] ET AL) 9 November 2006 (2006-11-09) paragraph [0165]; figure 1c -----	1-15

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
- "E" earlier application or patent but published on or after the international filing date
- "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)
- "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

- "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
- "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
- "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
- "&" document member of the same patent family

Date of the actual completion of the international search
13 July 2022

Date of mailing of the international search report
22/07/2022

Name and mailing address of the ISA/
 European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040,
 Fax: (+31-70) 340-3016

Authorized officer
Louarn, Arzhur

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2022/054146

Patent document cited in search report	B2	Publication date	Patent family member(s)	Publication date
US 9731089	B2	15-08-2017	EP 3104921 A1	21-12-2016
			US 2015231349 A1	20-08-2015
			WO 2015123112 A1	20-08-2015

US 9937309	B2	10-04-2018	EP 3171923 A1	31-05-2017
			US 2016022937 A1	28-01-2016
			WO 2016014532 A1	28-01-2016

WO 2019063744	A1	04-04-2019	CN 111163823 A	15-05-2020
			EP 3687609 A1	05-08-2020
			JP 2020534946 A	03-12-2020
			US 2019099571 A1	04-04-2019
			WO 2019063744 A1	04-04-2019

US 2006249149	A1	09-11-2006	EP 1605998 A1	21-12-2005
			JP 2006520227 A	07-09-2006
			US 2006249149 A1	09-11-2006
			WO 2004082751 A1	30-09-2004
