



(51) International Patent Classification:
A61B 5/11 (2006.01)

(21) International Application Number:
PCT/AU2017/050859

(22) International Filing Date:
14 August 2017 (14.08.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2016903225 15 August 2016 (15.08.2016) AU

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(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, 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,

(54) Title: APPARATUS AND METHODS FOR MONITORING CARDIO-RESPIRATORY DISORDERS

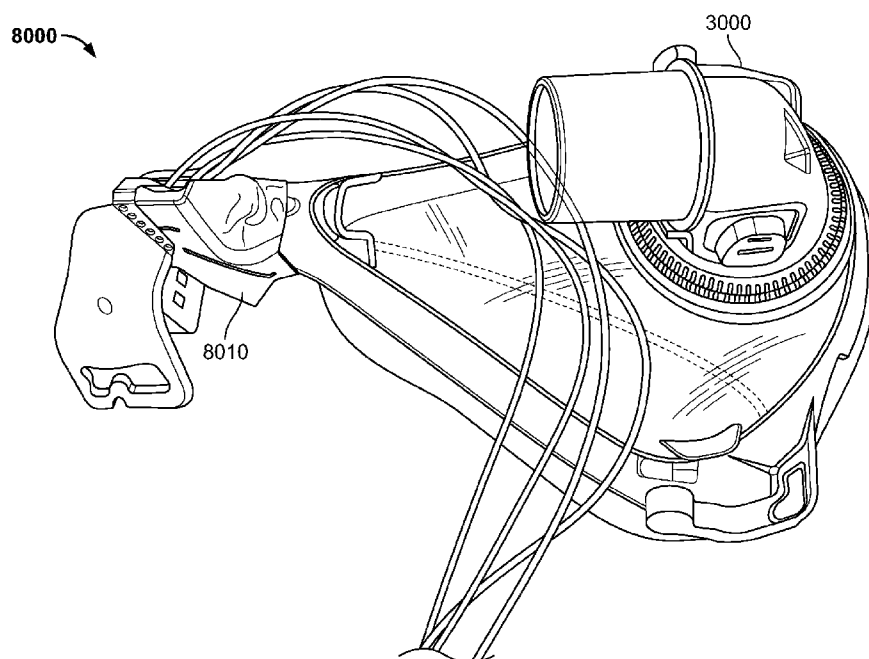


FIG. 8

(57) Abstract: A cardio-respiratory monitoring system comprises a patient interface, a monitoring device and a processor. The monitoring device comprises a gyroscope mounted on the patient interface so as to generate a ballistocardiography signal when a patient is wearing the patient interface. The processor is configured to analyse the ballistocardiography signal to estimate a heart rate of the patient. In one form of the technology the analysis carried out by the processor comprises partitioning the ballistocardiography signal into non-overlapping windows, detecting one or more peaks within a window, and estimating the heart rate as a reciprocal of the duration between consecutive detected peaks.



SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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))*

APPARATUS AND METHODS FOR MONITORING CARDIO-RESPIRATORY DISORDERS

1 CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of Australian Provisional Patent Application No. AU 2016903225, filed 15 August 2016, the entire disclosure of which is hereby incorporated herein by reference.

2 BACKGROUND OF THE TECHNOLOGY

2.1 FIELD OF THE TECHNOLOGY

[0002] The present technology relates to methods and apparatus for monitoring cardio-respiratory disorders. More particularly, some forms of the technology relate to measuring cardiac parameters of patients using sensors mounted on masks.

2.2 DESCRIPTION OF THE RELATED ART

2.2.1 Human Respiratory System and its Disorders

[0003] The respiratory system of the body facilitates gas exchange. The nose and mouth form the entrance to the airways of a patient.

[0004] The airways include a series of branching tubes, which become narrower, shorter and more numerous as they penetrate deeper into the lung. The prime function of the lung is gas exchange, allowing oxygen to move from the inhaled air into the venous blood and carbon dioxide to move in the opposite direction. The trachea divides into right and left main bronchi, which further divide eventually into terminal bronchioles. The bronchi make up the conducting airways, and do not take part in gas exchange. Further divisions of the airways lead to the respiratory bronchioles, and eventually to the alveoli. The alveolated region of the lung is where the gas exchange takes place, and is referred to as the respiratory zone. See “*Respiratory Physiology*”, by John B. West, Lippincott Williams & Wilkins, 9th edition published 2012.

[0005] A range of cardio-respiratory disorders exist. Examples of cardio-respiratory disorders include Obstructive Sleep Apnea (OSA), Cheyne-Stokes Respiration (CSR), heart failure, respiratory failure, and Chronic Obstructive Pulmonary Disease (COPD).

[0006] Obstructive Sleep Apnea (OSA), a form of Sleep Disordered Breathing (SDB), is characterised by events including occlusion or obstruction of the upper air passage during sleep. It results from a combination of an abnormally small upper airway and the normal loss of muscle tone in the region of the tongue, soft palate and posterior oropharyngeal wall during sleep. The disorder causes the affected patient to stop breathing for periods typically of 30 to 120 seconds in duration, sometimes 200 to 300 times per night. It often causes excessive daytime somnolence, and it may cause cardiovascular disease and brain damage. The syndrome is a common disorder, particularly in middle aged overweight males, although a person affected may have no awareness of the problem. See US Patent No. 4,944,310 (Sullivan).

[0007] Cheyne-Stokes Respiration (CSR) is another form of sleep disordered breathing. CSR is a disorder of a patient's respiratory controller in which there are rhythmic alternating periods of waxing and waning ventilation known as CSR cycles. CSR is characterised by repetitive de-oxygenation and re-oxygenation of the arterial blood. It is possible that CSR is harmful because of the repetitive hypoxia. In some patients CSR is associated with repetitive arousal from sleep, which causes severe sleep disruption, increased sympathetic activity, and increased afterload. See US Patent No. 6,532,959 (Berthon-Jones).

[0008] Heart failure is a relatively common and severe clinical disorder, characterised by the inability of the heart to keep up with the oxygen demands of the body. Management of heart failure is a significant challenge to modern healthcare systems due to its high prevalence and severity. Heart failure is a chronic disorder, which is progressive in nature. The progression of heart failure is often characterised as relatively stable over long periods of time (albeit with reduced cardiovascular function) punctuated by episodes of an acute nature. In these acute episodes, the patient experiences worsening of symptoms such as dyspnea (difficulty breathing), gallop rhythms, increased jugular venous pressure, and orthopnea. This is typically accompanied by overt congestion (which is the buildup of fluid in the pulmonary cavity). This excess fluid often leads to measurable weight gain of several kilograms. In many cases, however, by the time overt congestion has occurred, there are limited options for the doctor to help restabilize the patients, and in many cases the patient

requires hospitalization. In extreme cases, without timely treatment, the patient may undergo acute decompensated heart failure (ADHF) events.

[0009] Respiratory failure is an umbrella term for respiratory disorders in which the lungs are unable to inspire sufficient oxygen or exhale sufficient CO₂ to meet the patient's needs. Respiratory failure may encompass some or all of the following disorders. A patient with respiratory insufficiency (a form of respiratory failure) may experience abnormal shortness of breath on exercise.

[0010] Chronic Obstructive Pulmonary Disease (COPD) encompasses any of a group of lower airway diseases that have certain characteristics in common. These include increased resistance to air movement, extended expiratory phase of respiration, and loss of the normal elasticity of the lung. Examples of COPD are emphysema and chronic bronchitis. COPD is caused by chronic tobacco smoking (primary risk factor), occupational exposures, air pollution and genetic factors. Symptoms include: dyspnea on exertion, chronic cough and sputum production.

[0011] A range of therapies have been used to treat or ameliorate such disorders. However, these have a number of shortcomings.

2.2.2 Therapies

[0012] Various respiratory pressure therapies, such as Continuous Positive Airway Pressure (CPAP) therapy, Non-invasive ventilation (NIV) and Invasive ventilation (IV) have been used to treat one or more of the above cardio-respiratory disorders.

[0013] Continuous Positive Airway Pressure (CPAP) therapy has been used to treat Obstructive Sleep Apnea (OSA). The mechanism of action is that continuous positive airway pressure acts as a pneumatic splint and may prevent upper airway occlusion, such as by pushing the soft palate and tongue forward and away from the posterior oropharyngeal wall. Treatment of OSA by CPAP therapy may be voluntary, and hence patients may elect not to comply with therapy if they find devices used to provide such therapy one or more of: uncomfortable, difficult to use, expensive and aesthetically unappealing.

[0014] Non-invasive ventilation (NIV) provides ventilatory support to a patient through the upper airways to assist the patient breathing and/or maintain adequate oxygen levels in the body by doing some or all of the work of breathing. The ventilatory support is provided via a non-invasive patient interface. NIV has been used to treat CSR, respiratory failure, and COPD. In some forms, the comfort and effectiveness of these therapies may be improved.

2.2.3 Treatment Systems

[0015] These therapies may be provided by a treatment system or device. Such systems and devices may also be used to screen, diagnose, or monitor a disorder without treating it.

[0016] A treatment system may comprise a Respiratory Pressure Therapy Device (RPT device), an air circuit, a humidifier, and a patient interface.

2.2.3.1 Patient Interface

[0017] A patient interface may be used to interface respiratory equipment to its wearer, for example by providing a flow of air to an entrance to the airways. The flow of air may be provided via a mask to the nose and/or mouth, a tube to the mouth or a tracheostomy tube to the trachea of a patient. Depending upon the therapy to be applied, the patient interface may form a seal, e.g., with a region of the patient's face, to facilitate the delivery of gas at a pressure at sufficient variance with ambient pressure to effect therapy, e.g., at a positive pressure of about 10 cmH₂O relative to ambient pressure. For other forms of therapy, such as the delivery of oxygen, the patient interface may not include a seal sufficient to facilitate delivery to the airways of a supply of gas at a positive pressure of about 10 cmH₂O.

2.2.3.2 Respiratory Pressure Therapy (RPT) Device

[0018] A respiratory pressure therapy (RPT) device may be used individually or as part of a system to implement one or more of a number of therapies described above, such as by operating the device to generate a flow of air for delivery to an interface to the airways. The flow of air may be pressurised. Examples of RPT devices include a CPAP device and a ventilator.

2.2.3.3 Humidifier

[0019] Delivery of a flow of air without humidification may cause drying of airways. The use of a humidifier with an RPT device and the patient interface produces humidified gas that minimizes drying of the nasal mucosa and increases patient airway comfort. In addition in cooler climates, warm air applied generally to the face area in and about the patient interface is more comfortable than cold air.

2.2.4 Screening, Diagnosis, and Monitoring Systems

[0020] Screening and diagnosis generally describe the identification of a disorder from its signs and symptoms. Screening typically gives a true / false result indicating whether or not a patient's SDB is severe enough to warrant further investigation, while diagnosis may result in clinically actionable information. Screening and diagnosis tend to be one-off processes, whereas monitoring the progress of a disorder can continue indefinitely. Some screening / diagnosis systems are suitable only for screening / diagnosis, whereas some may also be used for monitoring.

[0021] It is of interest to be able to monitor cardio-respiratory disorders such as heart failure without necessarily actively treating them. Physiological parameters that have been proposed or used for the purpose of monitoring cardio-respiratory disorders include body weight, levels of B natriuretic peptides (BNP), nocturnal heart rate, changes in sleeping posture, and changes in respiration.

[0022] Polysomnography (PSG) is a conventional system for diagnosis and monitoring of cardio-respiratory disorders, and typically involves expert clinical staff to apply the system. PSG typically involves the placement of 15 to 20 contact sensors on a patient in order to record various bodily signals such as electroencephalography (EEG), electrocardiography (ECG or EKG), electrooculography (EOG), electromyography (EMG), etc. In particular, cardiac parameters such as nocturnal heart rate are often measured from an electrocardiogram. Electrocardiography is a transthoracic interpretation of the electrical activity of the heart over time performed by detecting the electrical activity from skin electrodes. The ECG detects the activity of the heart by amplifying the small electrical changes at the skin of the chest that are caused when the heart muscle depolarizes during each heartbeat. Changes in voltage

attributable to the electrical changes are detected by two electrodes placed on either side of the heart.

[0023] However, while they may be suitable for their usual application in a clinical setting, PSG systems are complicated and potentially expensive, and / or may be uncomfortable or impractical for a patient at home trying to sleep.

[0024] It will be appreciated that there is a need in the art for improved methods and apparatus for measuring cardiac parameters, in particular in patients who are receiving respiratory pressure therapy via a non-invasive patient interface.

3 BRIEF SUMMARY OF THE TECHNOLOGY

[0025] The present technology is directed towards providing medical devices used in the screening, diagnosis, or monitoring of cardio-respiratory disorders having one or more of improved comfort, cost, efficacy, ease of use and manufacturability.

[0026] In particular, the present technology comprises apparatus and methods for measuring cardiac parameters such as heart rate of a patient during sleep, by analysing biosignals generated by one or more sensors mounted on a patient interface such as a patient interface configured to deliver respiratory pressure therapy to the patient from a respiratory therapy device. In particular, the sensor may be a ballistocardiography sensor and the biosignal a ballistocardiography signal.

[0027] In accordance with one form of the technology, a method of estimating a heart rate of a patient wearing a patient interface is provided. The method comprises analysing a ballistocardiography signal from a gyroscope mounted on the patient interface to estimate the heart rate of the patient.

[0028] In some examples, analysing comprises partitioning the ballistocardiography signal into non-overlapping windows, detecting one or more peaks within a window, and estimating the heart rate as a reciprocal of the duration between consecutive detected peaks. Further, in some examples when plural peaks are detected within the window, the peak that gives a heart rate estimate closest to a previous heart rate estimate is used to estimate the heart rate.

[0029] In some examples, analysing comprises applying a Hilbert transform to the ballistocardiography signal. Analysing in other examples may comprise thresholding the ballistocardiography signal using a movement artefact threshold. In further examples, analysing comprises band-pass filtering the ballistocardiography signal.

[0030] In other examples, analysing comprises analysing a plurality of ballistocardiography signals from a three-axis gyroscope mounted on the patient interface to estimate the heart rate of the patient. In this and other examples, analysing comprises combining the plurality of ballistocardiography signals into a magnitude ballistocardiography signal. In further examples, analysing comprises partitioning each ballistocardiography signal into non-overlapping windows, detecting one or more peaks within a window of each ballistocardiography signal, and estimating the heart rate for each ballistocardiography signal as a reciprocal of the duration between consecutive detected peaks.

[0031] In some examples, when plural peaks are detected within the window, the peak that gives a heart rate estimate closest to a previous heart rate estimate is used to estimate the heart rate. In further examples, analysing comprises applying a Hilbert transform to each ballistocardiography signal. In still further examples, analysing comprises thresholding each ballistocardiography signal using a movement artefact threshold. Analysing may also comprise band-pass filtering each ballistocardiography signal. Other examples of analysing comprises fusing respective heart rate estimates from the plurality of ballistocardiography signals to estimate the heart rate of the patient. In addition, fusing comprises computing a custom weighted average of the respective heart rate estimates from the plurality of ballistocardiography signals.

[0032] In some examples, the method comprises computing a weighting for a heart rate estimate as a function of a difference between the heart rate estimate and a previous heart rate estimate for the patient.

[0033] In other examples, fusing comprises applying a Kalman filter to the respective heart rate estimates from the plurality of ballistocardiography signals. In addition, in further examples, a prediction model of the Kalman filter is that the heart rate remains constant.

[0034] In another form, the technology is a cardio-respiratory monitoring system. The system comprises a patient interface and a monitoring device comprising a gyroscope mounted on the patient interface so as to generate a ballistocardiography signal when a patient is wearing the patient interface. A processor is configured to analyse the ballistocardiography signal to estimate a heart rate of the patient.

[0035] In some examples, the gyroscope is mounted so that the axis of the gyroscope is the medial-lateral axis of the patient interface.

[0036] In other examples, the monitoring device further comprises a memory. The memory comprises program instructions adapted to configure the processor to analyse the ballistocardiography signal to estimate the heart rate of the patient. In other examples, the memory comprises program instructions adapted to configure the processor to store data representative of the ballistocardiography signal in the memory.

[0037] In some examples, the monitoring device further comprises a communication interface adapted to communicate with an external remote computing device. In addition, the processor forms part of the external remote computing device.

[0038] In some examples, the gyroscope is a three-axis gyroscope, and the processor is configured to analyse a plurality of ballistocardiography signals generated by the three-axis gyroscope to estimate the heart rate of the patient.

[0039] In another form, the technology is a cardio-respiratory monitoring device comprising: means for generating a ballistocardiography signal when mounted on a patient interface and the patient interface is being worn by a patient; and means for analysing the ballistocardiography signal to estimate a heart rate of the patient.

[0040] In some examples, the means for generating generates a plurality of ballistocardiography signals when mounted on the patient interface and the patient interface is being worn by a patient, and the means for analysing analyses the plurality of ballistocardiography signals to estimate the heart rate of the patient.

[0041] The methods, systems, devices and apparatus described may be implemented so as to improve the functionality of a processor, such as a processor of

a specific purpose computer, respiratory monitor and/or a respiratory therapy apparatus. Moreover, the described methods, systems, devices and apparatus can provide improvements in the technological field of automated management, monitoring and/or treatment of cardio-respiratory disorders, including, for example, sleep disordered breathing.

[0042] Of course, portions of the aspects may form sub-aspects of the present technology. Also, various ones of the sub-aspects and/or aspects may be combined in various manners and also constitute additional aspects or sub-aspects of the present technology.

[0043] Other features of the technology will be apparent from consideration of the information contained in the following detailed description, abstract, drawings and claims.

4 BRIEF DESCRIPTION OF THE DRAWINGS

[0044] The present technology is illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings, in which like reference numerals refer to similar elements including:

4.1 TREATMENT SYSTEMS

[0045] Fig. 1 shows a patient and a respiratory therapy system.

4.2 RESPIRATORY SYSTEM AND FACIAL ANATOMY

[0046] Fig. 2 shows an overview of a human respiratory system including the nasal and oral cavities, the larynx, vocal folds, oesophagus, trachea, bronchus, lung, alveolar sacs, heart and diaphragm.

4.3 PATIENT INTERFACE

[0047] Fig. 3 shows a patient interface in the form of a nasal mask in accordance with one form of the present technology.

4.4 RPT DEVICE

[0048] Fig. 4A shows an RPT device in accordance with one form of the present technology.

[0049] Fig. 4B is a schematic diagram of the pneumatic path of an RPT device in accordance with one form of the present technology.

[0050] Fig. 4C is a schematic diagram of the electrical components of an RPT device in accordance with one form of the present technology.

4.5 HUMIDIFIER

[0051] Fig. 5A shows an isometric view of a humidifier in accordance with one form of the present technology.

[0052] Fig. 5B shows an isometric view of a humidifier in accordance with one form of the present technology, showing a humidifier reservoir 5110 removed from the humidifier reservoir dock 5130.

4.6 BREATHING WAVEFORMS

[0053] Fig. 6 shows a model typical breath waveform of a person while sleeping.

4.7 SCREENING /DIAGNOSIS / MONITORING SYSTEMS

[0054] Fig. 7 shows a patient undergoing polysomnography (PSG).

[0055] Fig. 8 illustrates an unobtrusive cardio-respiratory screening / diagnosis / monitoring system according to one form of the present technology.

[0056] Fig. 9 is a block diagram illustrating a monitoring device that may be used in the monitoring system of Fig. 8 according to one form of the present technology.

[0057] Fig. 10 is a flowchart illustrating a method of analysing the three component BCG signals generated by the BCG sensor of the monitoring device of Fig. 9 to estimate the heart rate of a patient in one form of the present technology.

[0058] Fig. 11 is a graph illustrating the operation of the method of Fig. 10 with the CWA fusion step on example BCG data.

[0059] Fig. 12 is a graph illustrating the operation of the method of Fig. 10 with the KF fusion step on example BCG data.

5 DETAILED DESCRIPTION OF EXAMPLES OF THE TECHNOLOGY

[0060] Before the present technology is described in further detail, it is to be understood that the technology is not limited to the particular examples described herein, which may vary. It is also to be understood that the terminology used in this disclosure is for the purpose of describing only the particular examples discussed herein, and is not intended to be limiting.

[0061] The following description is provided in relation to various examples which may share one or more common characteristics and/or features. It is to be understood that one or more features of any one example may be combinable with one or more features of another example or other examples. In addition, any single feature or combination of features in any of the examples may constitute a further example.

5.1 TREATMENT SYSTEMS

[0062] Fig. 1 shows a patient 1000 wearing a patient interface 3000, in the form of a full-face mask, receiving a supply of air at positive pressure from an RPT device 4000. Air from the RPT device is humidified in a humidifier 5000, and passes along an air circuit 4170 to the patient 1000.

5.2 PATIENT INTERFACE

[0063] A non-invasive patient interface 3000, e.g., as shown in Figs. 1 and 3, in accordance with one aspect of the present technology comprises the following functional aspects: a seal-forming structure 3100, a plenum chamber 3200, a positioning and stabilising structure 3300, a vent 3400, one form of connection port 3600 for connection to air circuit 4170, and a forehead support 3700. In some forms a functional aspect may be provided by one or more physical components. In some forms, one physical component may provide one or more functional aspects. In use the seal-forming structure 3100 is arranged to surround an entrance to the airways of the patient so as to facilitate the supply of air at positive pressure to the airways.

5.3 RPT DEVICE

[0064] An RPT device 4000 in accordance with one aspect of the present technology comprises mechanical, pneumatic, and/or electrical components, and may be configured to execute one or more algorithms, such as any of the methods, in whole or in part, described herein. The RPT device 4000 may be configured to generate a flow of air for delivery to a patient's airways, such as to treat one or more of the cardio-respiratory disorders described elsewhere in the present document.

[0065] The RPT device, e.g., as shown in Figs. 4A – 4C, may have an external housing 4010, formed in two parts, an upper portion 4012 and a lower portion 4014. Furthermore, the external housing 4010 may include one or more panel(s) 4015. The RPT device 4000 comprises a chassis 4016 that supports one or more internal components of the RPT device 4000. The RPT device 4000 may include a handle 4018.

[0066] The pneumatic path of the RPT device 4000 may comprise one or more air path items, e.g., an inlet air filter 4112, an inlet muffler 4122, a pressure generator 4140 capable of supplying air at positive pressure (e.g., a blower 4142), an outlet muffler 4124 and one or more transducers 4270, such as pressure sensors 4272 and flow rate sensors 4274.

[0067] One or more of the air path items may be located within a removable unitary structure which will be referred to as a pneumatic block 4020. The pneumatic block 4020 may be located within the external housing 4010. In one form a pneumatic block 4020 is supported by, or formed as part of the chassis 4016.

[0068] The RPT device 4000 may have an electrical power supply 4210, one or more input devices 4220, a central controller 4230, a therapy device controller 4240, a pressure generator 4140, one or more protection circuits 4250, memory 4260, transducers 4270, data communication interface 4280 and one or more output devices 4290. Electrical components 4200 may be mounted on a single Printed Circuit Board Assembly (PCBA) 4202. In an alternative form, the RPT device 4000 may include more than one PCBA 4202.

5.3.1 RPT device mechanical & pneumatic components

[0069] Fig. 4B is a schematic diagram of the pneumatic path of an RPT device in accordance with one form of the present technology. The directions of upstream and downstream are indicated with reference to the blower and the patient interface. The blower is defined to be upstream of the patient interface and the patient interface is defined to be downstream of the blower, regardless of the actual flow direction at any particular moment. Items which are located within the pneumatic path between the blower and the patient interface are downstream of the blower and upstream of the patient interface.

[0070] An RPT device may comprise one or more of the following components in an integral unit. In an alternative form, one or more of the following components may be located as respective separate units.

5.3.1.1 Air filter(s)

[0071] An RPT device in accordance with one form of the present technology may include an air filter 4110, or a plurality of air filters 4110.

[0072] In one form, an inlet air filter 4112 is located at the beginning of the pneumatic path upstream of a pressure generator 4140.

[0073] In one form, an outlet air filter 4114, for example an antibacterial filter, is located between an outlet of the pneumatic block 4020 and a patient interface 3000.

5.3.1.2 Muffler(s)

[0074] An RPT device in accordance with one form of the present technology may include a muffler 4120, or a plurality of mufflers 4120.

[0075] In one form of the present technology, an inlet muffler 4122 is located in the pneumatic path upstream of a pressure generator 4140.

[0076] In one form of the present technology, an outlet muffler 4124 is located in the pneumatic path between the pressure generator 4140 and a patient interface 3000.

5.3.1.3 Pressure generator

[0077] In one form of the present technology, a pressure generator 4140 for producing a flow, or a supply, of air at positive pressure is a controllable blower 4142. For example the blower 4142 may include a brushless DC motor 4144 with one or more impellers housed in a blower housing, such as in a volute. The blower may be capable of delivering a supply of air, for example at a rate of up to about 120 litres/minute, at a positive pressure in a range from about 4 cmH₂O to about 20 cmH₂O, or in other forms up to about 30 cmH₂O. The blower may be as described in any one of the following patents or patent applications the contents of which are incorporated herein by reference in their entirety: U.S. Patent No. 7,866,944; U.S. Patent No. 8,638,014; U.S. Patent No. 8,636,479; and PCT Patent Application Publication No. WO 2013/020167.

[0078] The pressure generator 4140 is under the control of the therapy device controller 4240.

[0079] In other forms, a pressure generator 4140 may be a piston-driven pump, a pressure regulator connected to a high pressure source (e.g. compressed air reservoir), or a bellows.

5.3.1.4 Transducer(s)

[0080] Transducers may be internal of the RPT device, or external of the RPT device. External transducers may be located for example on or form part of the air circuit, e.g., the patient interface. External transducers may be in the form of non-contact sensors such as a Doppler radar movement sensor that transmit or transfer data to the RPT device.

[0081] In one form of the present technology, one or more transducers 4270 are located upstream and/or downstream of the pressure generator 4140. The one or more transducers 4270 may be constructed and arranged to generate signals representing properties of the flow of air such as a flow rate, a pressure or a temperature at that point in the pneumatic path.

[0082] In one form of the present technology, one or more transducers 4270 may be located proximate to the patient interface 3000.

[0083] In one form, a signal from a transducer 4270 may be filtered, such as by low-pass, high-pass or band-pass filtering.

5.3.1.4.1 Flow rate sensor

[0084] A flow rate sensor 4274 in accordance with the present technology may be based on a differential pressure transducer, for example, an SDP600 Series differential pressure transducer from SENSIRION.

[0085] In one form, a signal representing a flow rate from the flow rate sensor 4274 is received by the central controller 4230.

5.3.1.4.2 Pressure sensor

[0086] A pressure sensor 4272 in accordance with the present technology is located in fluid communication with the pneumatic path. An example of a suitable pressure sensor is a transducer from the HONEYWELL ASDX series. An alternative suitable pressure sensor is a transducer from the NPA Series from GENERAL ELECTRIC.

[0087] In one form, a signal from the pressure sensor 4272 is received by the central controller 4230.

5.3.1.4.3 Motor speed transducer

[0088] In one form of the present technology a motor speed transducer 4276 is used to determine a rotational velocity of the motor 4144 and/or the blower 4142. A motor speed signal from the motor speed transducer 4276 may be provided to the therapy device controller 4240. The motor speed transducer 4276 may, for example, be a speed sensor, such as a Hall effect sensor.

5.3.1.5 Anti-spill back valve

[0089] In one form of the present technology, an anti-spill back valve 4160 is located between the humidifier 5000 and the pneumatic block 4020. The anti-spill back valve is constructed and arranged to reduce the risk that water will flow upstream from the humidifier 5000, for example to the motor 4144.

5.3.2 RPT device electrical components

5.3.2.1 Power supply

[0090] A power supply 4210 may be located internal or external of the external housing 4010 of the RPT device 4000.

[0091] In one form of the present technology, power supply 4210 provides electrical power to the RPT device 4000 only. In another form of the present technology, power supply 4210 provides electrical power to both RPT device 4000 and humidifier 5000.

5.3.2.2 Input devices

[0092] In one form of the present technology, an RPT device 4000 includes one or more input devices 4220 in the form of buttons, switches or dials to allow a person to interact with the device. The buttons, switches or dials may be physical devices, or software devices accessible via a touch screen. The buttons, switches or dials may, in one form, be physically connected to the external housing 4010, or may, in another form, be in wireless communication with a receiver that is in electrical connection to the central controller 4230.

[0093] In one form, the input device 4220 may be constructed and arranged to allow a person to select a value and/or a menu option.

5.3.2.3 Central controller

[0094] In one form of the present technology, the central controller 4230 is one or a plurality of processors suitable to control an RPT device 4000.

[0095] Suitable processors may include an x86 INTEL processor, a processor based on ARM® Cortex®-M processor from ARM Holdings such as an STM32 series microcontroller from ST MICROELECTRONIC. In certain alternative forms of the present technology, a 32-bit RISC CPU, such as an STR9 series microcontroller from ST MICROELECTRONICS or a 16-bit RISC CPU such as a processor from the MSP430 family of microcontrollers, manufactured by TEXAS INSTRUMENTS may also be suitable.

[0096] In one form of the present technology, the central controller 4230 is a dedicated electronic circuit.

[0097] In one form, the central controller 4230 is an application-specific integrated circuit. In another form, the central controller 4230 comprises discrete electronic components.

[0098] The central controller 4230 may be configured to receive input signal(s) from one or more transducers 4270, one or more input devices 4220, and the humidifier 5000.

[0099] The central controller 4230 may be configured to provide output signal(s) to one or more of an output device 4290, a therapy device controller 4240, a data communication interface 4280, and the humidifier 5000.

[0100] In some forms of the present technology, the central controller 4230 is configured to execute one or more algorithms expressed as computer programs stored in a non-transitory computer readable storage medium, such as memory 4260.

5.3.2.4 Clock

[0101] The RPT device 4000 may include a clock 4232 that is connected to the central controller 4230.

5.3.2.5 Therapy device controller

[0102] In one form of the present technology, therapy device controller 4240 is a therapy control module that forms part of the algorithms executed by the central controller 4230.

[0103] In one form of the present technology, therapy device controller 4240 is a dedicated motor control integrated circuit. For example, in one form a MC33035 brushless DC motor controller, manufactured by ONSEMI is used.

5.3.2.6 Protection circuits

[0104] The one or more protection circuits 4250 in accordance with the present technology may comprise an electrical protection circuit, a temperature and/or pressure safety circuit.

5.3.2.7 Memory

[0105] In accordance with one form of the present technology the RPT device 4000 includes memory 4260, e.g., non-volatile memory. In some forms, memory 4260 may include battery powered static RAM. In some forms, memory 4260 may include volatile RAM.

[0106] Memory 4260 may be located on the PCBA 4202. Memory 4260 may be in the form of EEPROM, or NAND flash.

[0107] Additionally or alternatively, RPT device 4000 includes a removable form of memory 4260, for example a memory card made in accordance with the Secure Digital (SD) standard.

[0108] In one form of the present technology, the memory 4260 acts as a non-transitory computer readable storage medium on which is stored computer program instructions expressing the one or more methodologies described herein, such as the one or more algorithms executed by the central controller 4230.

5.3.2.8 Data communication systems

[0109] In one form of the present technology, a data communication interface 4280 is provided, and is connected to the central controller 4230. Data communication interface 4280 may be connectable to a remote external communication network 4282 and/or a local external communication network 4284. The remote external communication network 4282 may be connectable to a remote external device 4286. The local external communication network 4284 may be connectable to a local external device 4288.

[0110] In one form, data communication interface 4280 is part of the central controller 4230. In another form, data communication interface 4280 is separate from the central controller 4230, and may comprise an integrated circuit or a processor.

[0111] In one form, remote external communication network 4282 is the Internet. The data communication interface 4280 may use wired communication (e.g. via Ethernet, or optical fibre) or a wireless protocol (e.g. CDMA, GSM, LTE) to connect to the Internet.

[0112] In one form, local external communication network 4284 utilises one or more communication standards, such as Bluetooth, or a consumer infrared protocol.

[0113] In one form, remote external device 4286 is one or more computers, for example a cluster of networked computers. In one form, remote external device 4286 may be virtual computers, rather than physical computers. In either case, such a remote external device 4286 may be accessible to an appropriately authorised person such as a clinician.

[0114] The local external device 4288 may be a personal computer, mobile phone, tablet or remote control.

5.3.2.9 Output devices including optional display, alarms

[0115] An output device 4290 in accordance with the present technology may take the form of one or more of a visual, audio and haptic unit. A visual display may be a Liquid Crystal Display (LCD) or Light Emitting Diode (LED) display.

5.3.2.9.1 Display driver

[0116] A display driver 4292 receives as an input the characters, symbols, or images intended for display on the display 4294, and converts them to commands that cause the display 4294 to display those characters, symbols, or images.

5.3.2.9.2 Display

[0117] A display 4294 is configured to visually display characters, symbols, or images in response to commands received from the display driver 4292. For example, the display 4294 may be an eight-segment display, in which case the display driver 4292 converts each character or symbol, such as the figure “0”, to eight logical signals indicating whether the eight respective segments are to be activated to display a particular character or symbol.

5.3.3 RPT device algorithms

[0118] As mentioned above, in some forms of the present technology, the central controller 4230 may be configured to execute one or more algorithms expressed as computer programs stored in a non-transitory computer readable storage medium, such as memory 4260.

5.4 AIR CIRCUIT

[0119] An air circuit 4170 in accordance with an aspect of the present technology is a conduit or a tube constructed and arranged to allow, in use, a flow of air to travel between two components such as RPT device 4000 and the patient interface 3000.

5.5 BREATHING WAVEFORMS

[0120] Fig. 6 shows a model typical breath waveform of a person while sleeping. The horizontal axis is time, and the vertical axis is respiratory flow rate. While the parameter values may vary, a typical breath may have the following approximate values: tidal volume V_t 0.5L, inhalation time T_i 1.6s, peak inspiratory flow rate Q_{peak} 0.4 L/s, exhalation time T_e 2.4s, peak expiratory flow rate Q_{peak} -0.5 L/s. The total duration of the breath, T_{tot} , is about 4s. The person typically breathes at a rate of about 15 breaths per minute (BPM), with Ventilation V_{ent} about 7.5 L/min. A typical duty cycle, the ratio of T_i to T_{tot} , is about 40%.

5.6 SCREENING / DIAGNOSIS / MONITORING SYSTEMS

5.6.1 Polysomnography

[0121] Fig. 7 shows a patient 1000 undergoing polysomnography (PSG). A PSG system comprises a headbox 2000 which receives and records signals from the following sensors: an EOG electrode 2015; an EEG electrode 2020; an ECG electrode 2025; a submental EMG electrode 2030; a snore sensor 2035; a respiratory inductance plethysmogram (respiratory effort sensor) 2040 on a chest band; a respiratory inductance plethysmogram (respiratory effort sensor) 2045 on an abdominal band; an oro-nasal cannula 2050 with oral thermistor; a photoplethysmograph (pulse oximeter) 2055; and a body position sensor 2060. The electrical signals are referred to a ground electrode (ISOG) 2010 positioned in the centre of the forehead.

5.6.2 Unobtrusive systems

[0122] A patient interface, e.g. 3000, being used to delivery respiratory pressure therapy to a patient presents a good opportunity to monitor the patient, as it is in constant contact with the patient during sleep, which is a period of minimal disturbance. Hence by mounting one or more sensors on a patient interface it is possible to monitor a cardio-respiratory disorder of a patient undergoing respiratory

pressure therapy unobtrusively, e.g., without any added discomfort beyond that already presented by the therapy.

[0123] Fig. 8 illustrates an unobtrusive cardio-respiratory screening / diagnosis / monitoring system 8000 according to one form of the present technology. The monitoring system 8000 comprises a monitoring device 8010 mounted on a patient interface 3000 in the form of a full-face mask. In Fig. 8, the monitoring device 8010 is mounted in the nasal bridge region of the full-face mask 3000, though other mounting locations are contemplated. In general, device 8010 may be mounted on or in any region of the full-face mask that provides a stable surface and allows the device 8010 to obtain reliable measurement data that may be used by the methodology discussed below. For example, with miniaturization device 8010 may comprise a chip that is mounted on a surface of the patient interface 3000.

[0124] The monitoring system 8000 is particularly suitable for unobtrusively monitoring a cardio-respiratory disorder of a patient undergoing respiratory pressure therapy.

[0125] Fig. 9 is a block diagram illustrating a monitoring device 9000 that may be used as the monitoring device 8010 in the monitoring system 8000 of Fig. 8 according to one form of the present technology.

[0126] The monitoring device 9000 contains a sensor 9060 that generates one or more biosignals of the patient 1000 wearing the patient interface 3000 during a monitoring session.

[0127] The monitoring device 9000 also contains a processor 9010 configured to execute encoded instructions. The monitoring device 9000 also contains a non-transitory computer readable memory / storage medium 9030. The memory 9030 may be the internal memory of the monitoring device 9000, such as RAM, flash memory or ROM. In some implementations, memory 9030 may also be a removable or external memory linked to the monitoring device 9000, such as an SD card, server, USB flash drive or optical disc, for example. In other implementations, memory 9030 can be a combination of external and internal memory. Memory 9030 includes stored data 9040 and control instructions (code) 9050 adapted to configure, when executed, the processor 9010 to execute algorithms. Stored data 9040 can include data

representing the biosignal(s) generated by the sensor 9060 during a monitoring session, and other data that is provided as a component part of an application. Processor control instructions 9050 can also be provided as a component part of an application. The processor 9010 is adapted to retrieve or read the code 9050 from the memory 9030 and execute the encoded instructions. In particular, the code 9050 may contain instructions that configure the processor 9010 to execute one or more methods of processing the biosignal(s) generated by the sensor 9060. One such processing method may be to record the biosignal(s) over the monitoring session, represented as data 9040 in the memory 9030. Another such method may be to analyse the biosignal(s), represented as the recorded session data thereof, to estimate one or more cardiac parameters of the patient 1000. One such analysis method is described in detail below. The processor 9010 may store the results of such analysis as data 9040 in the memory 9030.

[0128] The monitoring device 9000 also comprises a communication interface 9020. The code 9050 may contain instructions configured to allow the processor 9010 to communicate with an external remote computing device (not shown) via the communication interface 9020. The mode of communication may be wired or wireless. In one such implementation, the processor 9010 may transmit the recorded session data from the data 9040 to the remote computing device via the communication interface 9020. In such an implementation, a processor of the remote computing device may be configured to analyse the received session data to estimate the cardiac parameters. In another such implementation, the processor 9010 may transmit the analysis results from the data 9040 to the remote computing device via the communication interface 9020.

[0129] Alternatively, if the memory 9030 is removable from the monitoring device 9000, the remote computing device may be configured to be connectable to the removable memory 9030. In such an implementation, a processor of the remote computing device may be configured to analyse the recorded session data retrieved from the removable memory 9030 to estimate the cardiac parameters. Alternatively, the recorded session data may be stored in data 9040 of the memory 9030, permanently or temporarily, and transmitted via communication interface 9020 for analysis by the processor of the remote computing device. In either case, e.g.,

removal of the memory or transmittal of the session data, the system may be implemented and operate in a distributed architecture environment.

[0130] Ballistocardiography (BCG) is a technique for measuring a patient's cardiac parameters such as heart rate (HR) based on small recoil movements caused by blood being pumped around the body. BCG sensors are most commonly used for heart rate monitoring during sleep, since they are able to function as non-contact sensors when embedded into the patient's bedstead or mattress. This means that the patient does not need to wear the sensor in order to have their heart rate monitored, increasing the likelihood that the device will be used.

[0131] BCG sensors may convert a sensed force or pressure into an electrical signal, either by using an air pressure transducer or a material that has electrically resistive properties that vary in proportion to the applied force. BCG sensors are able to not only measure heart rate, but also measure respiration rate and detect movement episodes, both of which can be useful in sleep stage classification, as well as diagnosing sleep disorders such as OSA and insomnia.

[0132] Wearable BCG sensors have also been developed. Some of these sensors have been placed onto the patient's chest, and can not only measure a patient's heart rate, but can also detect and classify heart murmur. There have also been wearable BCG sensors developed for use on more distal locations, such as the head and wrist. Unlike the non-contact BCG sensors, most wearable BCG sensors have been developed for constant monitoring as opposed to sleep monitoring, which means they need to be able to cope with larger and more frequent movement artefacts.

[0133] In one implementation of the monitoring device 9000, the sensor 9060 is a wearable BCG sensor. The BCG sensor 9060 may be a three-axis gyroscope, such as contained in an MPU-9150 (manufactured by Invensense Inc., USA). A three-axis gyroscope provides three component BCG signals representing the instantaneous rotation rate (in degrees per second) of the gyroscope around three mutually orthogonal axes. The BCG signals are each sampled at the same sampling rate, e.g. 50 Hz.

[0134] The three orthogonal axes of the BCG sensor 9060 forming part of the monitoring device 9000 when mounted on the patient interface 3000 according to one

form of the present technology, as illustrated in Fig. 8, are as follows: the x-axis is the superior-inferior axis of the patient interface (superior being positive); the y-axis is the anterior-posterior axis of the patient interface (anterior being positive), and the z-axis is the medial-lateral axis of the patient interface (lateral being positive). The three component BCG signals, labelled as g_x , g_y , and g_z , represent rotational velocities around these three axes respectively. By using one or more of the rotational velocities measured by the BCG sensor 9060 and associated with the three component BCG signals, recoil movements caused by blood flow (the origin of ballistocardiography) or other movements of a patient may be detected and processed as discussed below to estimate heart rate. If the BCG sensor 9060 is mounted in a different orientation, e.g. with the x-axis being the anterior-posterior axis of the patient interface, the processing described below may still be used, with the three component BCG signals g_x , g_y , and g_z appropriately permuted so that, for example, g_z still represents the rotational velocity around the medial-lateral axis (lateral being positive).

[0135] In an alternative implementation, the BCG sensor 9060 may be a single-axis gyroscope. In such an implementation, the BCG sensor may be mounted on the patient interface 3000 such that the axis is the medial-lateral axis of the patient interface (lateral being positive). In such an implementation, the processing described below may still be used to estimate heart rate from the single component BCG signal g_z , leaving out steps 10010 and 10070.

[0136] The system 8000 further comprises one or more algorithms to estimate the heart rate of a patient from the component BCG signals generated by the BCG sensor 9060. The one or more algorithms may include data fusion algorithms for estimating a single heart rate from multiple heart rate estimates obtained from respective component BCG signals.

5.6.2.1 Analysis methods

[0137] Fig. 10 is a flow chart illustrating a method 10000 of analysing the three component BCG signals generated by the BCG sensor 9060 to estimate the heart rate of a patient. As mentioned above, the method 10000 may be implemented in code 9050 stored in the computer readable memory 9030 of the monitoring device 9000, and executed by the processor 9010 of the monitoring device 9000. Alternatively, the method 10000 may be executed by a processor of a remote computing device, which

receives the BCG signal data either from the communication interface 9020 of the monitoring device 9000, or from the removable memory 9030 of the monitoring device 9000 as described above.

[0138] The method 10000 starts at step 10010, where the three component BCG signals g_x , g_y , and g_z , are combined into a single magnitude BCG signal g_n . In one implementation, g_n is the Euclidean norm of the rotational velocity vector $[g_x \ g_y \ g_z]$. The subsequent steps 10020 to 10060 are all carried out independently on each of the four BCG signals g_x , g_y , g_z , and g_n , except step 10020, which is only carried out on the three component BCG signals g_x , g_y , and g_z .

[0139] In some implementations, step 10010 may be omitted and steps 10020 to 10060 carried out on some subset comprising one or more of the three component BCG signals g_x , g_y , and g_z .

[0140] Step 10020 applies the Hilbert transform to the three component BCG signals g_x , g_y , and g_z . The Hilbert transform is applied as the BCG forces resulting from a heartbeat tend to cause the head to wobble, which can be more difficult to reliably detect than a peak. The Hilbert transform of step 10020 is able to transform this wobble in the three component BCG signals g_x , g_y , and g_z into a peak, which is easier to detect.

[0141] Step 10030 applies a band-pass filter to the three transformed BCG signals and to the magnitude BCG signal g_n to reduce high frequency motion artefacts, vibration from unwanted sources, and baseline drift. In one implementation, step 10030 uses a second order Butterworth filter with cut-off frequencies of 0.5 and 10 Hz.

[0142] Step 10040 thresholds the four filtered BCG signals to remove large movement artefacts so that the dominant peaks in the resulting BCG signals correspond to heartbeats and not head or other limb movements. For each BCG signal, step 10040 first calculates a movement artefact threshold. The movement artefact threshold is calculated in an initialization period at the start of the session. The threshold calculation may be made by defining a number of non-overlapping consecutive windows of fixed width at the start of the BCG signal. Values for the number of these windows typically range between 3 and 10, e.g. size, while the width

of the windows is chosen so that the initialisation period typically lasts between 5 and 15 seconds, e.g. 9 seconds. The maximum value of the BCG signal for each window is calculated, and the average of these maximum values may be taken as the movement artefact threshold. The movement artefact threshold is then applied by setting any part of the BCG signal larger than the movement artefact threshold to zero.

[0143] Step 10050 integrates (e.g., low-pass filters) the four thresholded BCG signals within a sliding window in order to further reduce unwanted noise in the BCG signals. (The integration of step 10050 is optionally preceded by a squaring operation to increase signal to noise ratio.) In one implementation, a window width of 0.1 seconds may be used.

[0144] Finally, at step 10060, a beat-by-beat heart rate is estimated from each integrated BCG signal by detecting peaks in the integrated BCG signal, labelling the peaks as heartbeats, and measuring their frequency. In one implementation of step 10060, each integrated BCG signal is partitioned into non-overlapping windows. In one implementation, a window width of 1.5 seconds is used, as this width is large enough that for a patient with a normal HR (greater than 40 BPM), there will be at least one heartbeat per window. In other implementations, the window width could be up to 4 seconds. All of the heartbeats (peaks) within each window are detected for each of the integrated BCG signals. In one implementation, the method used to detect peaks in the integrated BCG signals is derived from the peak detection section of the Pan-Tompkins QRS detection algorithm [1]. For each detected heartbeat (peak) in an integrated BCG signal, a HR estimate may be calculated as the reciprocal of the duration between the currently detected heartbeat and the previous heartbeat for that integrated BCG signal. If multiple heartbeats are detected within a window, then the heartbeat that gives a HR value closest to the previous window's HR estimate is used. The beat-by-beat HR is a time series of HR estimates for a given integrated BCG signal, one HR estimate per window.

[0145] Any of the HR estimate time series from the four BCG signals g_x , g_y , g_z , and g_n may be taken as the beat-by-beat estimate of the heart rate of the patient. It has been found that the z-axis component g_z gives the best performance on its own. Alternatively, the four HR estimate times series, or some subset of the four, may be

fused using an optional data fusion step 10070 to produce a single HR estimate time series that should be more accurate than any of the four individual HR estimate time series.

[0146] In addition, before data fusion step 10070, a correction step may be implemented on all or some subset of the four HR estimate time series so as to correct estimates that are clearly incorrect. One example of such a correction step is a median filter.

[0147] In another example of a correction step before data fusion step 10070, outlier HRs may be discarded. Outlier HRs may be defined as HR values either greater than 200 BPM or less than 40 BPM. The upper limit may also be 150 BPM or some other high value. Although these values will naturally be given a low weighting by the data fusion step 10070, they may still contaminate the final estimate, particularly when a reliable HR estimate cannot be obtained from any BCG signal.

[0148] In one implementation of the data fusion step 10070, a Custom Weighted Average (CWA) approach is used. To apply CWA fusion, each HR estimate for each window is assigned a weighting between 0 and 1. The weighting $\sigma_{i,k}$ for BCG signal i ($i = 1$ to n , where n is the number of component estimates being fused) at window k may be calculated based on the difference between $HR_{i,k}$, the estimated HR for BCG signal i at window k , and the previous output HR_k of the CWA fusion. In one implementation, the weighting $\sigma_{i,k}$ may be calculated as

$$\sigma_{i,k} = \exp\left(-\frac{|HR_{i,k} - HR_{k-1}|}{C}\right) \quad (1.1)$$

[0149] where C is a constant. In one implementation, C may be chosen so that when the difference in the interbeat interval between two consecutive heartbeats is 0.2s, a weighting value of 0.75 is assigned to that heartbeat. This value was chosen in order to ensure that large variations in estimated heartbeats caused by noise and incorrect beat detection do not influence the final HR substantially, whilst still allowing for a relatively high weighting for differences in HR caused by the natural variation in HR.

[0150] Once the weightings $\sigma_{i,k}$ for BCG signal i at window k have been computed, the HR estimate HR_k for the window k may be computed as a weighted average of the HR estimates $HR_{i,k}$ at window k , wherein the weightings in the average are the squares of the weightings $\sigma_{i,k}$:

$$HR_k = \frac{\sum_{i=1}^n \sigma_{i,k}^2 HR_{i,k}}{\sum_{j=1}^n \sigma_{j,k}^2} \quad (1.2)$$

[0151] In another implementation of step 10070, a Kalman filtering (KF) approach is used. KF is a fusion technique that is able to take measurements from several sources and make an estimation on the state of a defined system based on those measurements. A Kalman filter consists of two sections, in which a prediction is made based on a defined model of the state to which the filter is applied, and then the prediction is updated based upon the current measurements. In one implementation, the prediction model is that the true HR (modelled by the single underlying state variable x) will remain constant from window $k-1$ to window k with some small random variation:

$$x_k = x_{k-1} + w_k \quad (1.3)$$

[0152] where x_k is the HR in window k , and w_k is drawn from a zero-mean Gaussian distribution with variance q_k . Other prediction models that more accurately reflect the dynamics of heart rate are also contemplated for use in the KF prediction model. The true state x_k is observed through the n HR estimates $HR_{i,k}$ at window k :

$$\mathbf{z}_k = H_k x_k + \mathbf{v}_k \quad (1.4)$$

[0153] where $\mathbf{z}_k$ is the observation n -vector of HR estimates $HR_{i,k}$ at window k , ($i = 1$ to n), H_k (the observation matrix) is a column vector of n ones, and $\mathbf{v}_k$ is defined as the observation noise, which is assumed also to be Gaussian, with zero mean and noise covariance matrix R_k .

[0154] Using the constant-HR prediction model, the prediction equations for KF are

$$\hat{x}_{k|k-1} = \hat{x}_{k-1|k-1} \quad (1.5)$$

[0155] and

$$P_{k|k-1} = P_{k-1|k-1} + q_k \quad (1.6)$$

[0156] where $\hat{x}_{k|k-1}$ is the estimate of the HR at window k based on the information known at window $k-1$, and P_k is a measure of the accuracy of the prediction. From these equations, the prediction is updated based on measurements taken at window k according to the following equations:

$$y_k = z_k - H_k \hat{x}_{k|k-1} \quad (1.7)$$

$$S_k = H_k P_{k|k-1} H_k^T + R_k \quad (1.8)$$

$$K_k = P_{k|k-1} H_k^T S_k^{-1} \quad (1.9)$$

$$\hat{x}_{k|k} = \hat{x}_{k|k-1} + K_k y_k \quad (1.10)$$

$$P_{k|k} = (I - K_k H_k) P_{k|k-1} \quad (1.11)$$

[0157] The observation noise covariance matrix R_k may be set to $\text{diag}(\sigma_{i,k})$ for $i = 1$ to n , where

$$\sigma_{i,k} = |HR_{i,k} - \hat{x}_{k-1|k-1}| \quad (1.12)$$

[0158] If the estimate $HR_{i,k}$ from the i -th BCG signal in the window k is equal to $\hat{x}_{k-1|k-1}$, then $\sigma_{i,k}$ may be set to 0.01, to avoid a zero value. This is because a zero value on the diagonal of the noise covariance matrix R_k can cause instability problems when inverting the matrix S_k .

[0159] The final HR estimate HR_k for window k is the a posteriori state estimate $\hat{x}_{k|k}$. In one implementation, to initialise the KF, $\hat{x}_{0|0}$ is set to a reasonable starting estimate based on the n HR estimates $HR_{i,1}$ for the first window, e.g. the median thereof, $P_{0|0}$ is set to 0.1, and q_k is set to 0.3 for all k . In general, the number of

observations n is 4 for the four BCG signals g_x , g_y , g_z , and g_n . However, if a heartbeat is not detected in the window k for a given BCG signal, or the BCG signal has had a heartbeat discarded, then the matrices are resized to $n = 3$ so that that BCG signal is not considered in the calculations at window k .

5.6.2.2 Results

[0160] Fig. 11 contains a graph 1100 illustrating the operation of the method 10000 of Fig. 10 with the CWA fusion step 10070 on example BCG signal data spanning about two minutes. The graph 1100 contains two traces: a trace 1110 that shows a reference HR time series estimated from ECG data, and a trace 1120 that shows the HR time series estimated from BCG data using the method 10000 of Fig. 10, using a CWA implementation of the optional data fusion step 10070. The ECG electrodes were placed on the patient's hand and right foot in a Lead I ECG configuration. The heartbeats were detected in the ECG data using the Pan-Tompkins algorithm [1]. The graph 1100 shows that the CWA HR trace 1120 closely follows the reference HR trace 1110, with a slight delay. The reference HR trace 1110 is a beat-by-beat HR in that the HR is updated every time a heartbeat is detected. However for the BCG HR trace 1120, the data fusion step 10070 produces a HR value that is updated every 1.5 seconds, regardless of how many heartbeats have occurred in that last 1.5 seconds. This will mean that if a heartbeat is detected in the BCG signal, it could be up to 1.5 seconds before that detected heartbeat is converted into a detected HR by the data fusion step 10070. This delay will not usually be significant in screening, diagnosis, and monitoring applications.

[0161] Fig. 12 contains a graph 1200 illustrating the operation of the method 10000 of Fig. 10 with the KF fusion step 10070 on the same example BCG signal data as used in Fig. 11. The graph 1200 contains two traces: a trace 1210 that shows a reference HR estimated from ECG data, and a trace 1220 that shows the HR estimated from BCG data using the method 10000 of Fig. 10, using a KF implementation of the optional data fusion step 10070. The graph 1200 shows that the KF HR trace 1220 closely follows the reference HR trace 1210, again with a slight delay.

5.7 GLOSSARY

[0162] For the purposes of the present technology disclosure, in certain forms of the present technology, one or more of the following definitions may apply. In other forms of the present technology, alternative definitions may apply.

5.7.1 General

[0163] *Air*: In certain forms of the present technology, air may be taken to mean atmospheric air, and in other forms of the present technology air may be taken to mean some other combination of breathable gases, e.g. atmospheric air enriched with oxygen.

[0164] *Ambient*: In certain forms of the present technology, the term ambient will be taken to mean (i) external of the treatment system or patient, and (ii) immediately surrounding the treatment system or patient.

[0165] *Flow rate*: The volume (or mass) of air delivered per unit time. Flow rate may refer to an instantaneous quantity. In some cases, a reference to flow rate will be a reference to a scalar quantity, namely a quantity having magnitude only. In other cases, a reference to flow rate will be a reference to a vector quantity, namely a quantity having both magnitude and direction. Flow rate may be given the symbol Q . 'Flow rate' is sometimes shortened to simply 'flow' or 'airflow'.

[0166] In the example of patient respiration, a flow rate may be nominally positive for the inspiratory portion of a breathing cycle of a patient, and hence negative for the expiratory portion of the breathing cycle of a patient. Total flow rate, Q_t , is the flow rate of air leaving the RPT device. Vent flow rate, Q_v , is the flow rate of air leaving a vent to allow washout of exhaled gases. Leak flow rate, Q_l , is the flow rate of leak from a patient interface system or elsewhere. Respiratory flow rate, Q_r , is the flow rate of air that is received into the patient's respiratory system.

[0167] *Humidifier*: A humidifying apparatus constructed and arranged, or configured with a physical structure to be capable of providing a therapeutically beneficial amount of water (H_2O) vapour to a flow of air to ameliorate a respiratory disorder of a patient.

[0168] *Patient*: A person, whether or not they are suffering from a cardio-respiratory disorder.

[0169] *Respiratory Pressure Therapy (RPT)*: The application of a supply of air to an entrance to the airways at a treatment pressure that is typically positive with respect to atmosphere.

[0170] *Ventilator*: A mechanical device that provides pressure support to a patient to perform some or all of the work of breathing.

5.7.2 Respiratory cycle

[0171] *Apnea*: According to some definitions, an apnea is said to have occurred when flow falls below a predetermined threshold for a duration, e.g. 10 seconds. An obstructive apnea will be said to have occurred when, despite patient effort, some obstruction of the airway does not allow air to flow. A central apnea will be said to have occurred when an apnea is detected that is due to a reduction in breathing effort, or the absence of breathing effort, despite the airway being patent. A mixed apnea occurs when a reduction or absence of breathing effort coincides with an obstructed airway.

[0172] *Breathing rate*: The rate of spontaneous respiration of a patient, usually measured in breaths per minute.

[0173] *Duty cycle*: The ratio of inhalation time, T_i to total breath time, T_{tot} .

[0174] *Effort (breathing)*: The work done by a spontaneously breathing person attempting to breathe.

[0175] *Expiratory portion of a breathing cycle*: The period from the start of expiratory flow to the start of inspiratory flow.

[0176] *Flow limitation*: Flow limitation will be taken to be the state of affairs in a patient's respiration where an increase in effort by the patient does not give rise to a corresponding increase in flow. Where flow limitation occurs during an inspiratory portion of the breathing cycle it may be described as inspiratory flow limitation. Where flow limitation occurs during an expiratory portion of the breathing cycle it may be described as expiratory flow limitation.

[0177] *Hypopnea*: According to some definitions, a hypopnea is taken to be a reduction in flow, but not a cessation of flow. In one form, a hypopnea may be said to have occurred when there is a reduction in flow below a threshold rate for a duration. A central hypopnea will be said to have occurred when a hypopnea is detected that is due to a reduction in breathing effort. In one form in adults, either of the following may be regarded as being hypopneas:

- (i) a 30% reduction in patient breathing for at least 10 seconds plus an associated 4% desaturation; or
- (ii) a reduction in patient breathing (but less than 50%) for at least 10 seconds, with an associated desaturation of at least 3% or an arousal.

[0178] *Hyperpnea*: An increase in flow to a level higher than normal.

[0179] *Inspiratory portion of a breathing cycle*: The period from the start of inspiratory flow to the start of expiratory flow will be taken to be the inspiratory portion of a breathing cycle.

[0180] *Patency (airway)*: The degree of the airway being open, or the extent to which the airway is open. A *patent* airway is open. Airway patency may be quantified, for example with a value of one (1) being patent, and a value of zero (0), being closed (obstructed).

[0181] *Positive End-Expiratory Pressure (PEEP)*: The pressure above atmosphere in the lungs that exists at the end of expiration.

[0182] *Peak flow rate (Q_{peak})*: The maximum value of flow rate during the inspiratory portion of the respiratory flow waveform.

[0183] *Respiratory flow rate, patient airflow rate, respiratory airflow rate (Q_r)*: These terms may be understood to refer to the RPT device's estimate of respiratory flow rate, as opposed to "true respiratory flow rate" or "true respiratory flow rate", which is the actual respiratory flow rate experienced by the patient, usually expressed in litres per minute.

[0184] *Tidal volume (V_t)*: The volume of air inhaled or exhaled during normal breathing, when extra effort is not applied. In principle the inspiratory volume V_i (the volume of air inhaled) is equal to the expiratory volume V_e (the volume of air exhaled), and therefore a single tidal volume V_t may be defined as equal to either quantity. In practice the tidal volume V_t is estimated as some combination, e.g. the mean, of the inspiratory volume V_i and the expiratory volume V_e .

[0185] *(inhalation) Time (T_i)*: The duration of the inspiratory portion of the respiratory flow rate waveform.

[0186] *(exhalation) Time (T_e)*: The duration of the expiratory portion of the respiratory flow rate waveform.

[0187] *(total) Time (T_{tot})*: The total duration between the start of one inspiratory portion of a respiratory flow rate waveform and the start of the following inspiratory portion of the respiratory flow rate waveform.

[0188] *Typical recent ventilation*: The value of ventilation around which recent values of ventilation V_{ent} over some predetermined timescale tend to cluster, that is, a measure of the central tendency of the recent values of ventilation.

[0189] *Upper airway obstruction (UAO)*: includes both partial and total upper airway obstruction. This may be associated with a state of flow limitation, in which the flow rate increases only slightly or may even decrease as the pressure difference across the upper airway increases (Starling resistor behaviour).

[0190] *Ventilation (V_{ent})*: A measure of a rate of gas being exchanged by the patient's respiratory system. Measures of ventilation may include one or both of inspiratory and expiratory flow, per unit time. When expressed as a volume per minute, this quantity is often referred to as "minute ventilation". Minute ventilation is sometimes given simply as a volume, understood to be the volume per minute.

5.8 OTHER REMARKS

[0191] A portion of the disclosure of this patent document contains material which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it

appears in Patent Office patent files or records, but otherwise reserves all copyright rights whatsoever.

[0192] Unless the context clearly dictates otherwise and where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit, between the upper and lower limit of that range, and any other stated or intervening value in that stated range is encompassed within the technology. The upper and lower limits of these intervening ranges, which may be independently included in the intervening ranges, are also encompassed within the technology, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the technology.

[0193] Furthermore, where a value or values are stated herein as being implemented as part of the technology, it is understood that such values may be approximated, unless otherwise stated, and such values may be utilized to any suitable significant digit to the extent that a practical technical implementation may permit or require it.

[0194] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this technology belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present technology, a limited number of the exemplary methods and materials are described herein.

[0195] When a particular material is identified as being used to construct a component, obvious alternative materials with similar properties may be used as a substitute. Furthermore, unless specified to the contrary, any and all components herein described are understood to be capable of being manufactured and, as such, may be manufactured together or separately.

[0196] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include their plural equivalents, unless the context clearly dictates otherwise.

[0197] All publications mentioned herein are incorporated herein by reference in their entirety to disclose and describe the methods and/or materials which are the subject of those publications. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present technology is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates, which may need to be independently confirmed.

[0198] The terms "comprises" and "comprising" should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced.

[0199] The subject headings used in the detailed description are included only for the ease of reference of the reader and should not be used to limit the subject matter found throughout the disclosure or the claims. The subject headings should not be used in construing the scope of the claims or the claim limitations.

[0200] Although the technology herein has been described with reference to particular examples, it is to be understood that these examples are merely illustrative of the principles and applications of the technology. In some instances, the terminology and symbols may imply specific details that are not required to practice the technology. For example, although the terms "first" and "second" may be used, unless otherwise specified, they are not intended to indicate any order but may be utilised to distinguish between distinct elements. Furthermore, although process steps in the methodologies may be described or illustrated in an order, such an ordering is not required. Those skilled in the art will recognize that such ordering may be modified and/or aspects thereof may be conducted concurrently or even synchronously.

[0201] It is therefore to be understood that numerous modifications may be made to the illustrative examples and that other arrangements may be devised without departing from the spirit and scope of the technology.

5.9 REFERENCE SIGNS LIST

patient	1000
graph	1100
reference HR trace	1110
CWA HR trace	1120
graph	1200
reference HR trace	1210
KF HR trace	1220
headbox	2000
ground electrode	2010
EOG electrode	2015
EEG electrode	2020
ECG electrode	2025
submental EMG electrode	2030
snore sensor	2035
effort sensor	2040
effort sensor	2045
oro - nasal cannula	2050
photoplethysmograph	2055
body position sensor	2060
patient interface	3000
seal - forming structure	3100
plenum chamber	3200
structure	3300
vent	3400
connection port	3600
forehead support	3700
RPT device	4000
external housing	4010
upper portion	4012
portion	4014
panel	4015
chassis	4016
handle	4018
pneumatic block	4020
air filter	4110
inlet air filter	4112
outlet air filter	4114
mufflers	4120
inlet muffler	4122
outlet muffler	4124
pressure generator	4140
blower	4142
motor	4144
anti - spill back valve	4160

air circuit	4170
electrical components	4200
PCBA	4202
electrical power supply	4210
input devices	4220
central controller	4230
clock	4232
therapy device controller	4240
protection circuits	4250
memory	4260
transducer	4270
pressure sensors	4272
flow rate sensor	4274
motor speed transducer	4276
data communication interface	4280
remote external communication network	4282
local external communication network	4284
remote external device	4286
local external device	4288
output device	4290
display driver	4292
display	4294
humidifier	5000
humidifier reservoir	5110
humidifier reservoir dock	5130
monitoring system	8000
monitoring device	8010
monitoring device	9000
processor	9010
communication interface	9020
memory	9030
data	9040
processor control instructions	9050
sensor	9060
method	10000
step	10010
step	10020
step	10030
step	10040
step	10050
step	10060
step	10070

6 CITATIONS

1. Pan, J. and Tompkins, W.J. *A real-time QRS detection algorithm*. IEEE Transactions on Biomedical Engineering, 1985(3): p. 230-236.

7 CLAIMS

1. A method of estimating a heart rate of a patient wearing a patient interface, the method comprising analysing a ballistocardiography signal from a gyroscope mounted on the patient interface to estimate the heart rate of the patient.
2. The method of claim 1, wherein the analysing comprises:
 - partitioning the ballistocardiography signal into non-overlapping windows,
 - detecting one or more peaks within a window, and
 - estimating the heart rate as a reciprocal of the duration between consecutive detected peaks.
3. The method of claim 2, wherein when plural peaks are detected within the window, the peak that gives a heart rate estimate closest to a previous heart rate estimate is used to estimate the heart rate.
4. The method of any of claims 1 to 3, wherein the analysing comprises applying a Hilbert transform to the ballistocardiography signal.
5. The method of any of claims 1 to 4, wherein the analysing comprises thresholding the ballistocardiography signal using a movement artefact threshold.
6. The method of any of claims 1 to 5, wherein the analysing comprises band-pass filtering the ballistocardiography signal.
7. The method of claim 1, wherein the analysing comprises analysing a plurality of ballistocardiography signals from a three-axis gyroscope mounted on the patient interface to estimate the heart rate of the patient.
8. The method of claim 7, wherein the analysing comprises combining the plurality of ballistocardiography signals into a magnitude ballistocardiography signal.
9. The method of any of claims 7 to 8, wherein the analysing comprises:
 - partitioning each ballistocardiography signal into non-overlapping windows,

detecting one or more peaks within a window of each ballistocardiography signal, and

estimating the heart rate for each ballistocardiography signal as a reciprocal of the duration between consecutive detected peaks.

10. The method of claim 9, wherein when plural peaks are detected within the window, the peak that gives a heart rate estimate closest to a previous heart rate estimate is used to estimate the heart rate.

11. The method of any of claims 7 to 10, wherein the analysing comprises applying a Hilbert transform to each ballistocardiography signal.

12. The method of any of claims 7 to 11, wherein the analysing comprises thresholding each ballistocardiography signal using a movement artefact threshold.

13. The method of any of claims 7 to 12, wherein the analysing comprises band-pass filtering each ballistocardiography signal.

14. The method of any of claims 7 to 13, wherein the analysing comprises fusing respective heart rate estimates from the plurality of ballistocardiography signals to estimate the heart rate of the patient.

15. The method of claim 14, wherein the fusing comprises computing a custom weighted average of the respective heart rate estimates from the plurality of ballistocardiography signals.

16. The method of claim 15, further comprising computing a weighting for a heart rate estimate as a function of a difference between the heart rate estimate and a previous heart rate estimate for the patient.

17. The method of claim 14, wherein the fusing comprises applying a Kalman filter to the respective heart rate estimates from the plurality of ballistocardiography signals.

18. The method of claim 17, wherein a prediction model of the Kalman filter is that the heart rate remains constant.

19. A cardio-respiratory monitoring system comprising:

a patient interface;

a monitoring device comprising a gyroscope mounted on the patient interface so as to generate a ballistocardiography signal when a patient is wearing the patient interface; and

a processor configured to analyse the ballistocardiography signal to estimate a heart rate of the patient.

20. The cardio-respiratory monitoring system of claim 19, wherein the gyroscope is mounted so that the axis of the gyroscope is the medial-lateral axis of the patient interface.

21. The cardio-respiratory monitoring system of any of claims 19 to 20, wherein the monitoring device further comprises a memory.

22. The cardio-respiratory monitoring system of claim 21, wherein the memory comprises program instructions adapted to configure the processor to analyse the ballistocardiography signal to estimate the heart rate of the patient.

23. The cardio-respiratory monitoring system of claim 21, wherein the memory comprises program instructions adapted to configure the processor to store data representative of the ballistocardiography signal in the memory.

24. The cardio-respiratory monitoring system of claim 23, wherein the monitoring device further comprises a communication interface adapted to communicate with an external remote computing device.

25. The cardio-respiratory monitoring system of claim 24, wherein the processor forms part of the external remote computing device.

26. The cardio-respiratory monitoring system of any of claims 19 to 25, wherein:

the gyroscope is a three-axis gyroscope, and

the processor is configured to analyse a plurality of ballistocardiography signals generated by the three-axis gyroscope to estimate the heart rate of the patient.

27. A cardio-respiratory monitoring device comprising:

a gyroscope configured to be mounted on a patient interface, the gyroscope configured to generate a ballistocardiography signal when mounted on the patient interface and the patient interface is being worn by a patient;

a processor; and

a memory comprising program instructions adapted to configure the processor to analyse the ballistocardiography signal to estimate a heart rate of the patient.

28. The cardio-respiratory monitoring device of claim 27, wherein:

the gyroscope comprises a three-axis gyroscope configured to generate a plurality of ballistocardiography signals when mounted on the patient interface and the patient interface is being worn by a patient, and

the program instructions are adapted to configure the processor to analyse the plurality of ballistocardiography signals to estimate the heart rate of the patient.

29. A cardio-respiratory monitoring device comprising:

means for generating a ballistocardiography signal when mounted on a patient interface and the patient interface is being worn by a patient; and

means for analysing the ballistocardiography signal to estimate a heart rate of the patient.

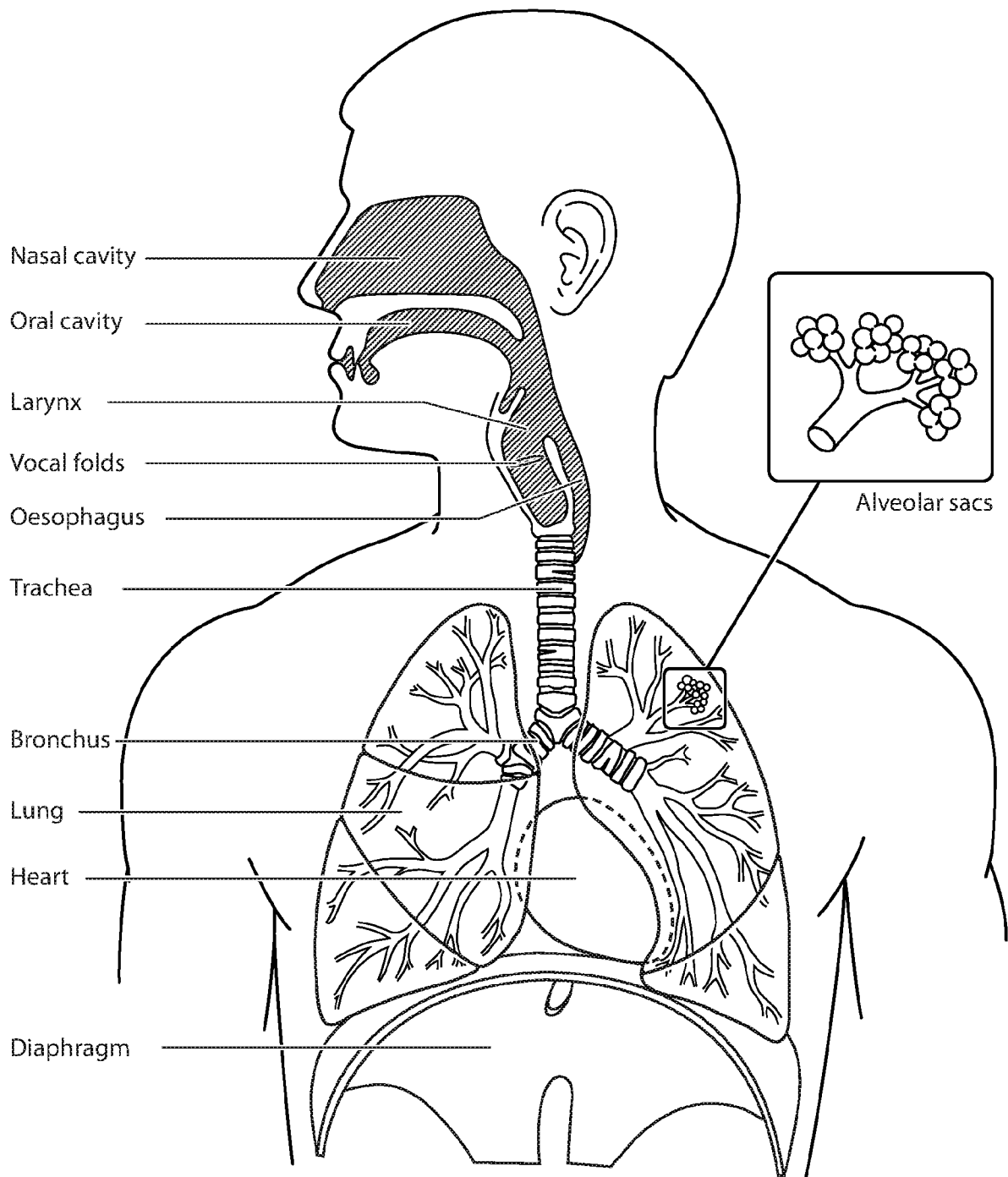
30. The cardio-respiratory monitoring device of claim 29, wherein:

the means for generating generates a plurality of ballistocardiography signals when mounted on the patient interface and the patient interface is being worn by a patient, and

the means for analysing analyses the plurality of ballistocardiography signals to estimate the heart rate of the patient.



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**FIG. 2**

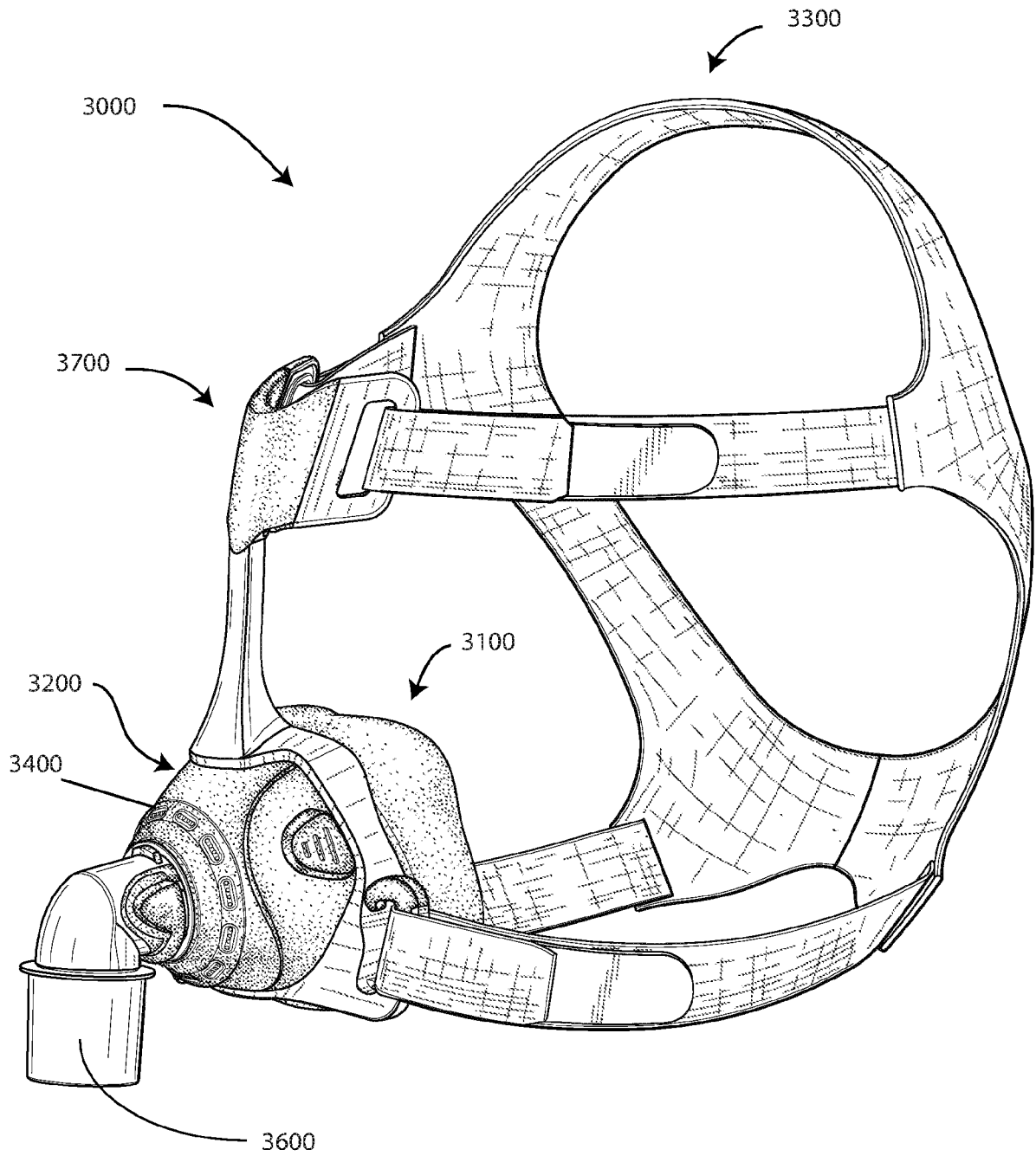
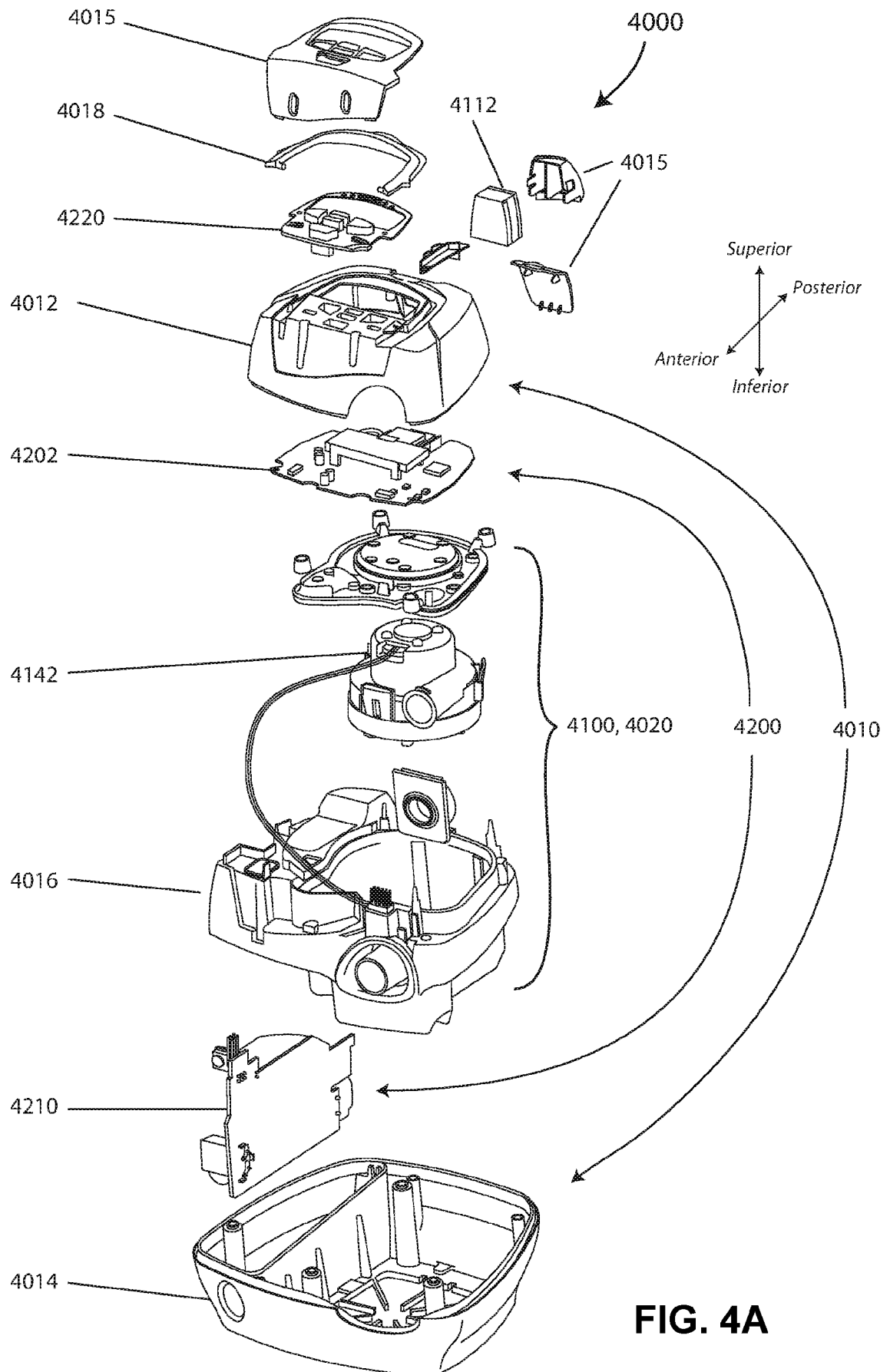
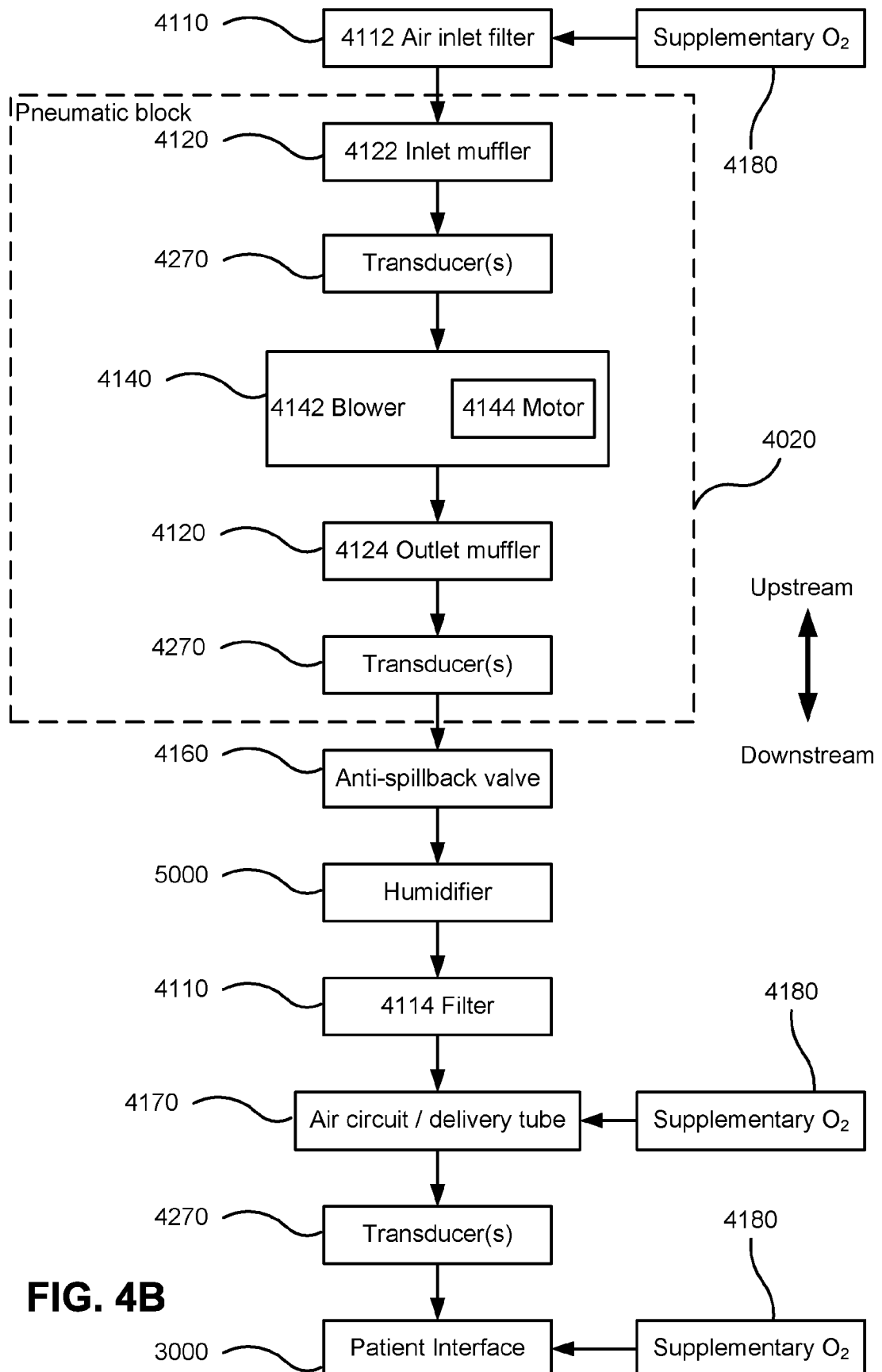


FIG. 3

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**FIG. 4B**

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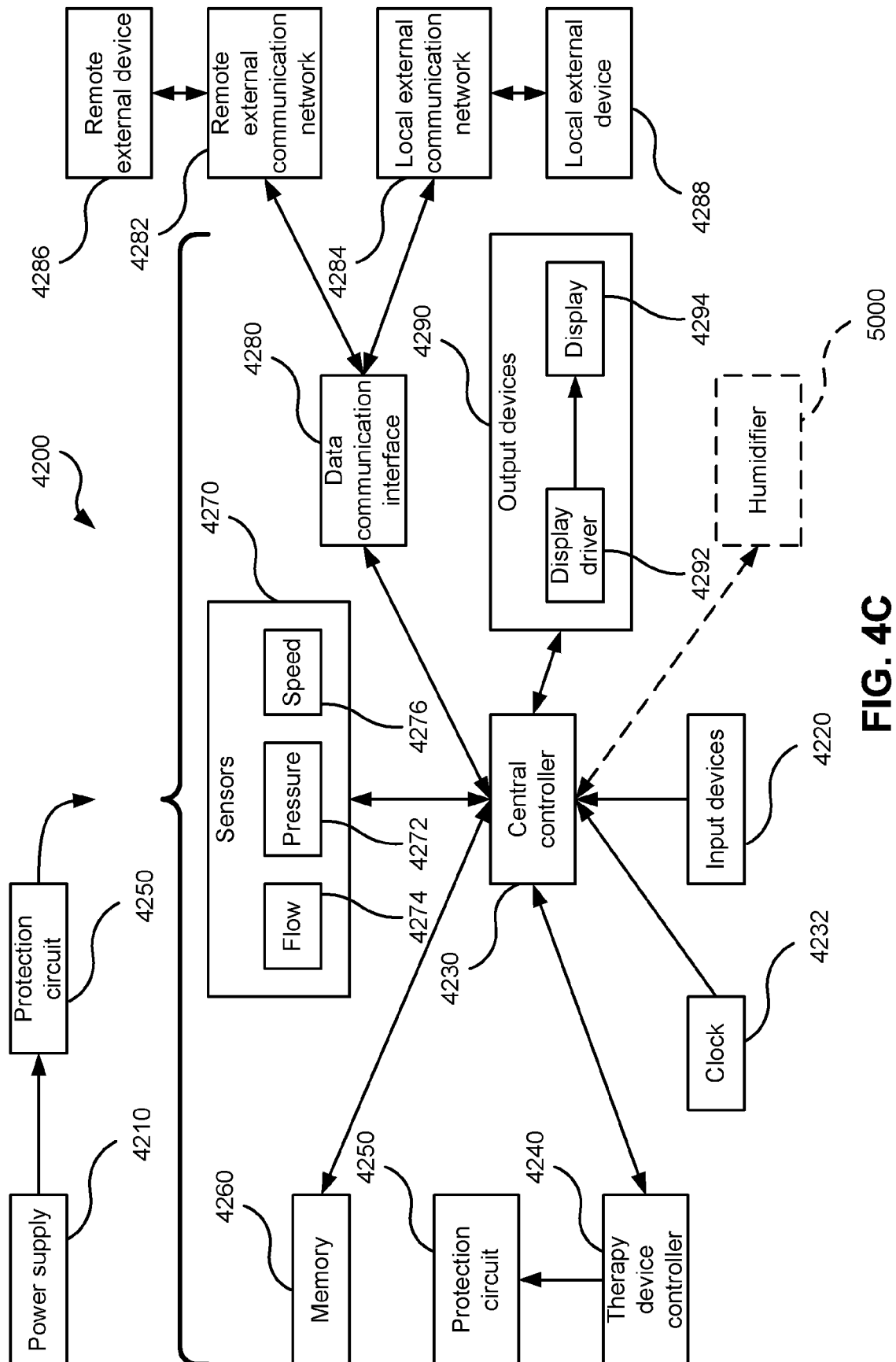
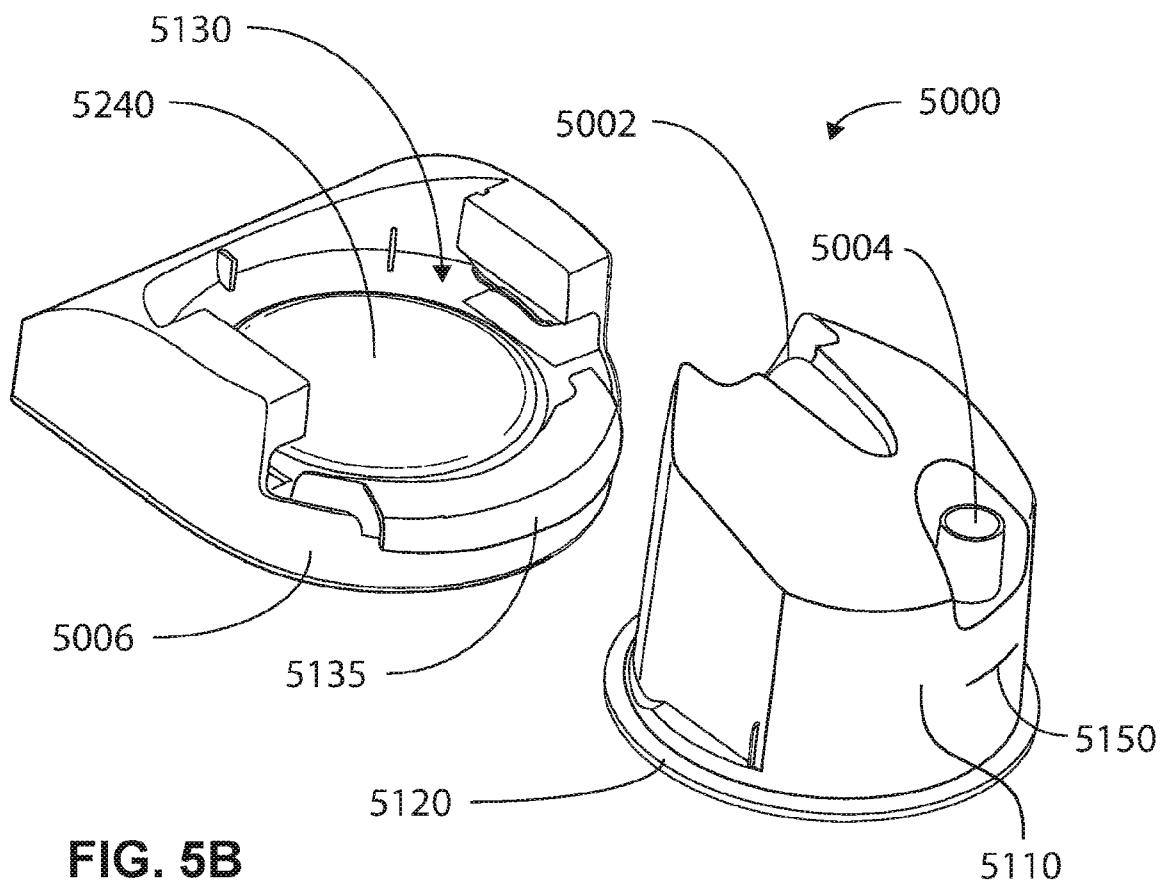
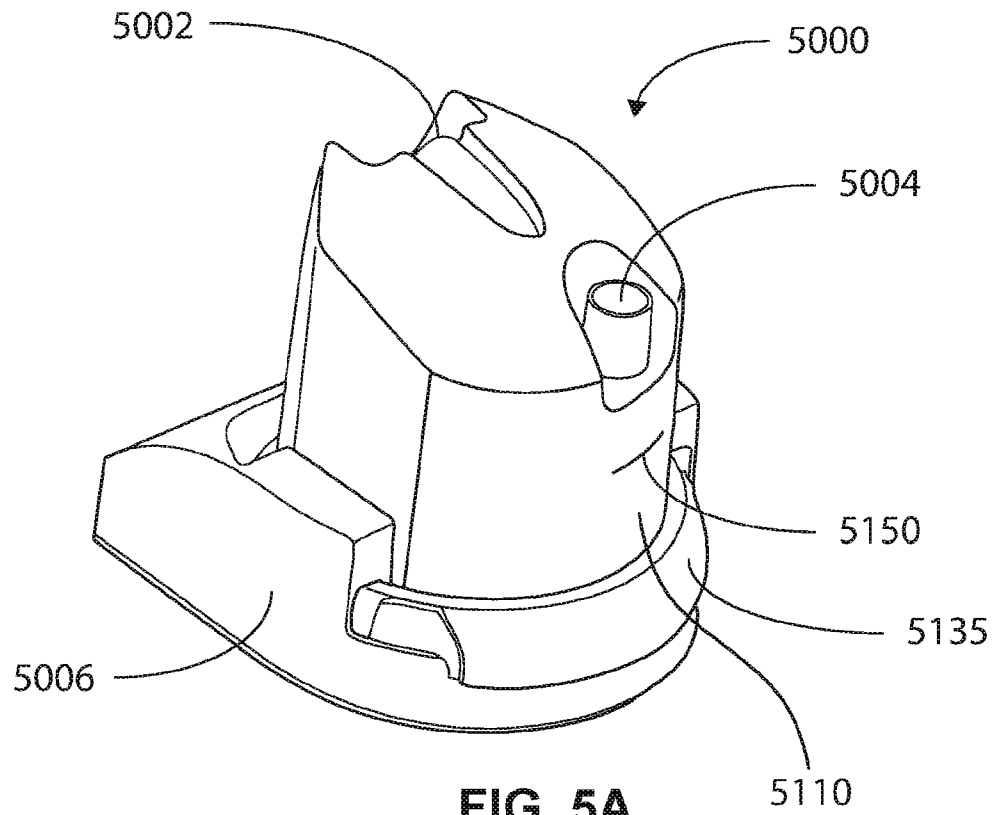


FIG. 4C

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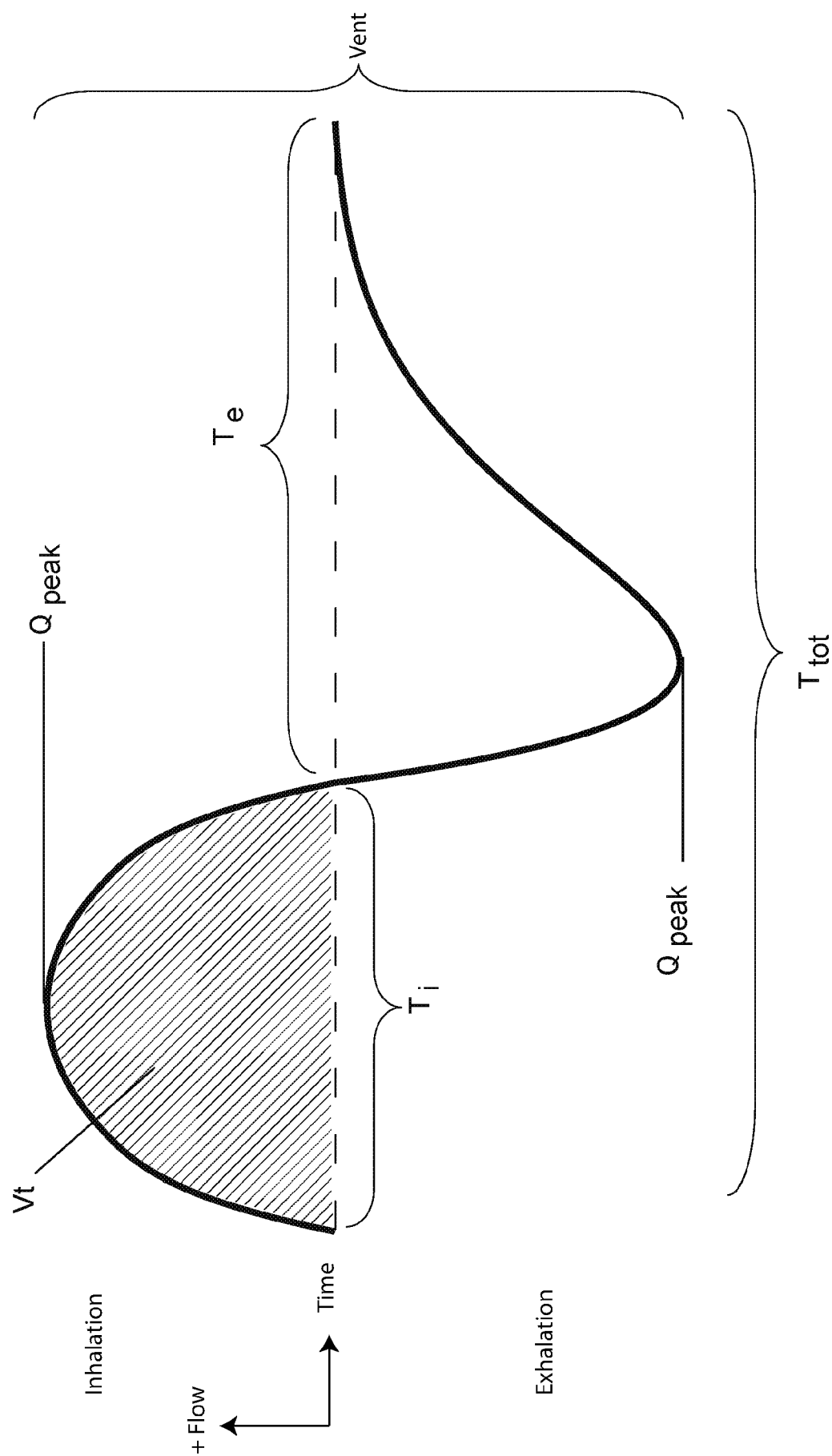
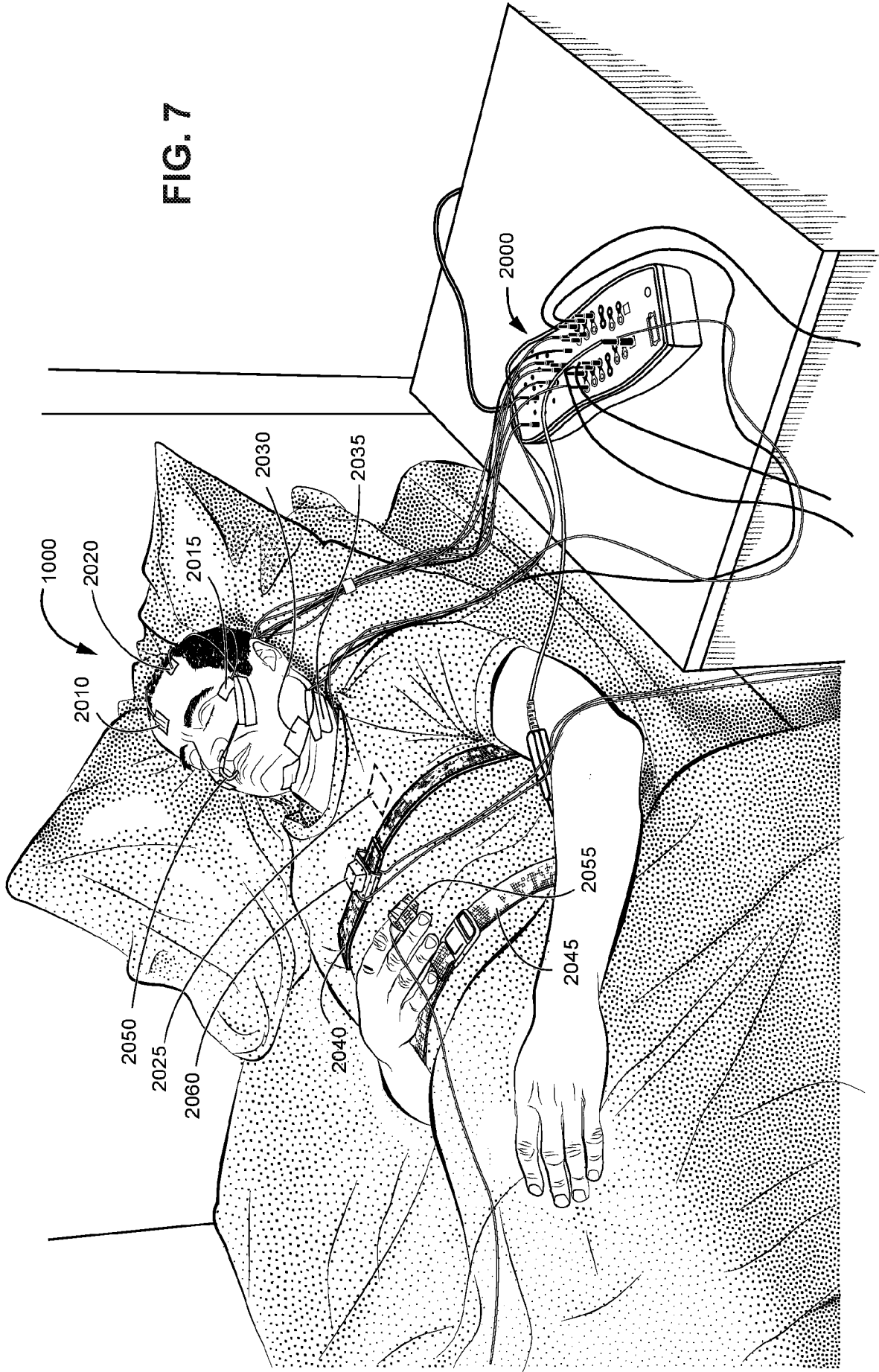
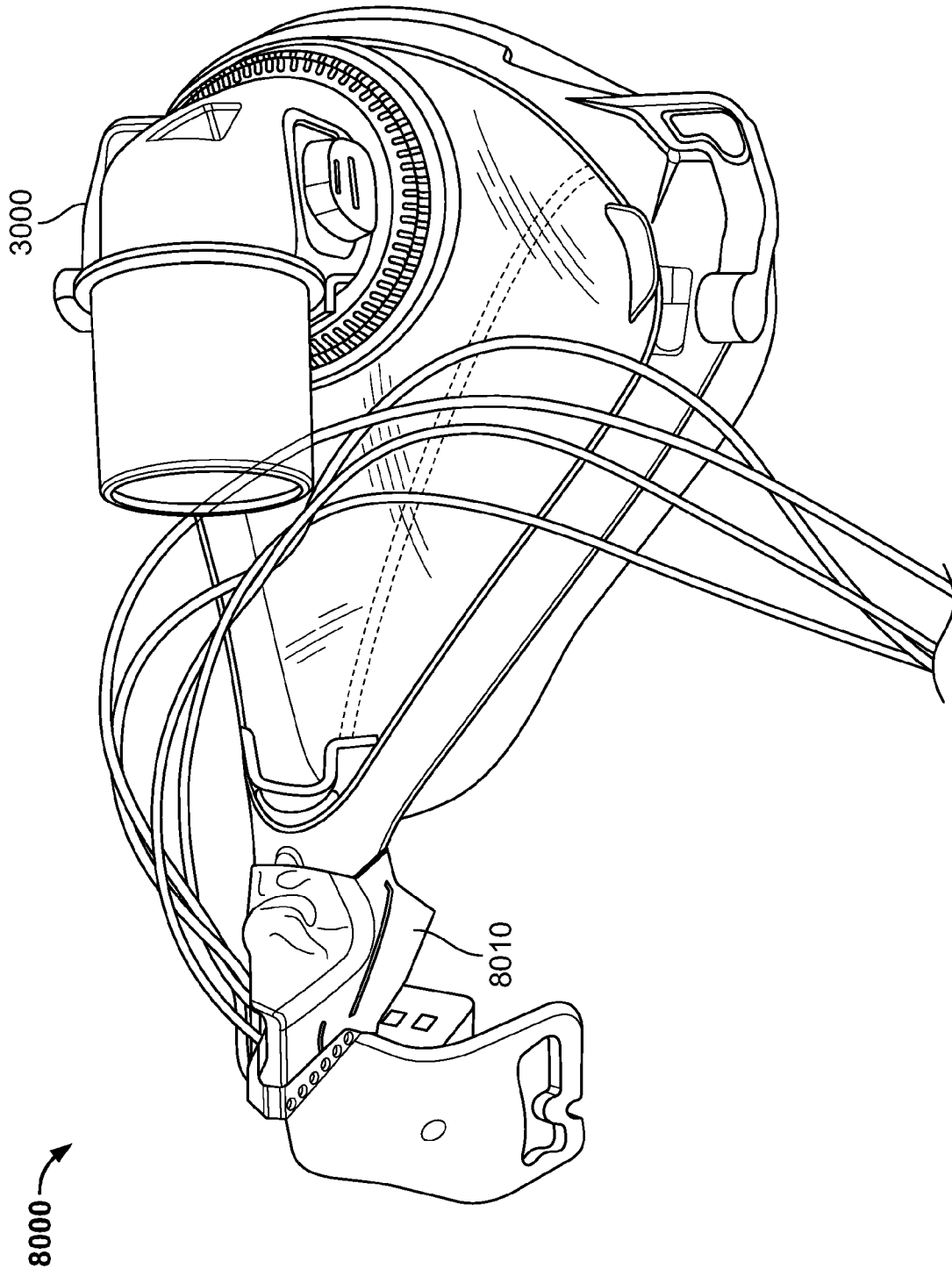


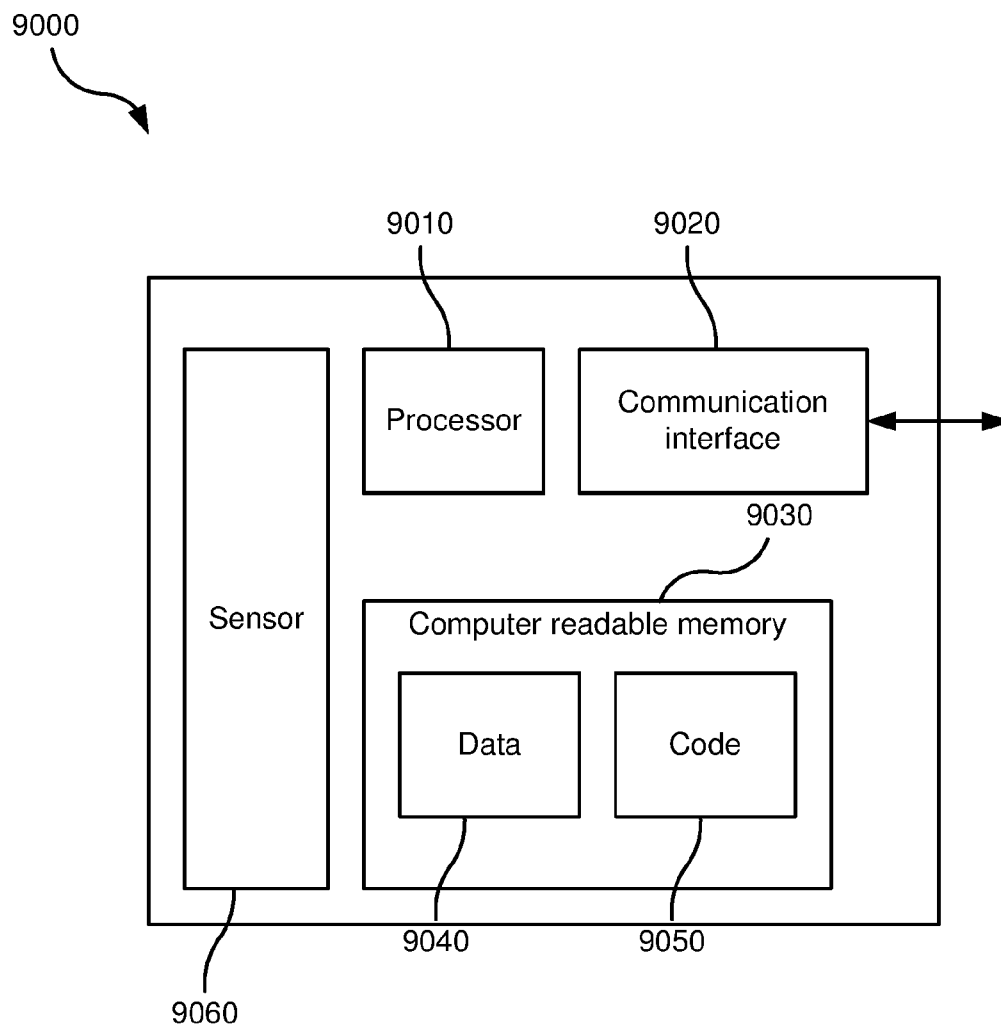
FIG. 6

FIG. 7

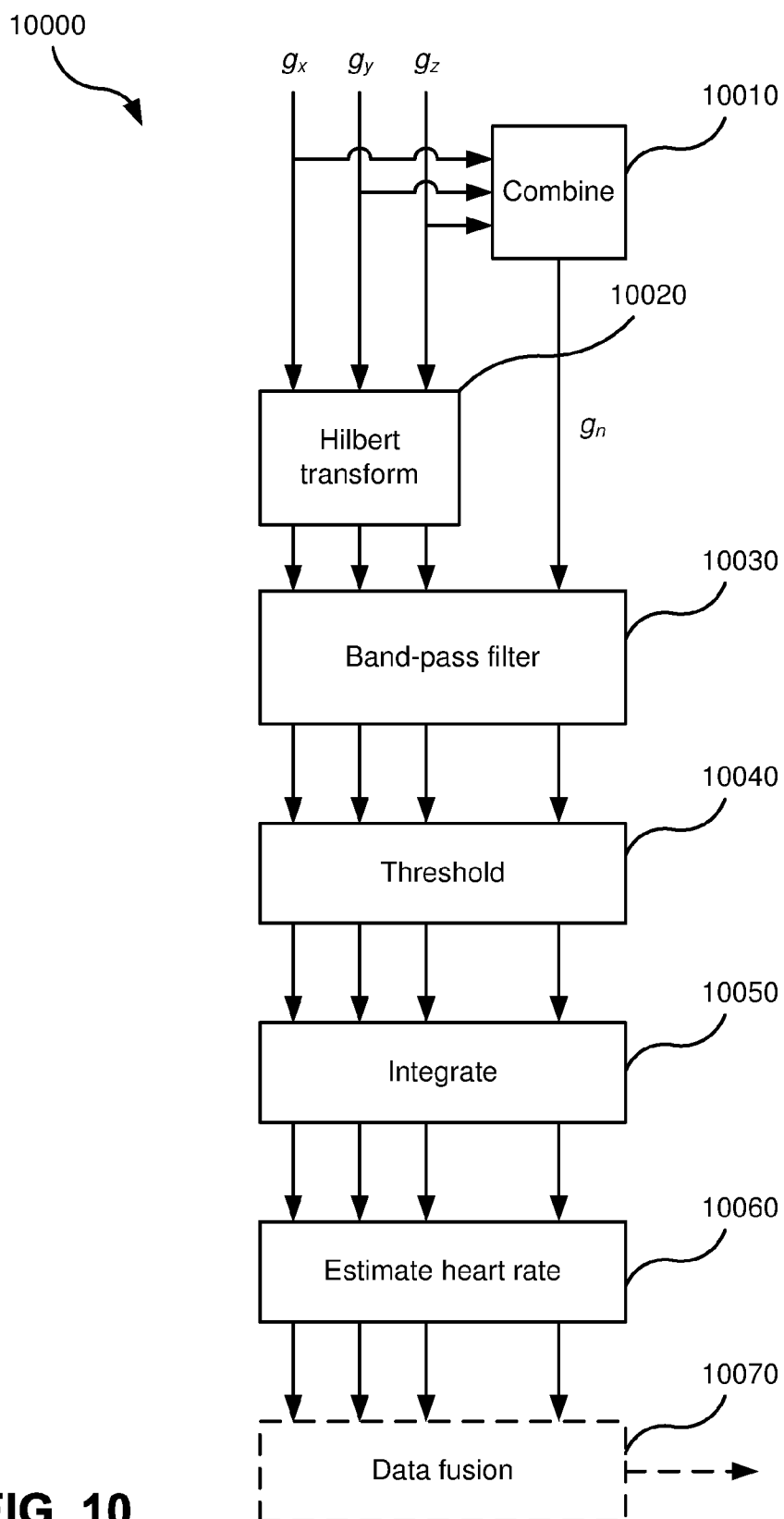




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**FIG. 9**

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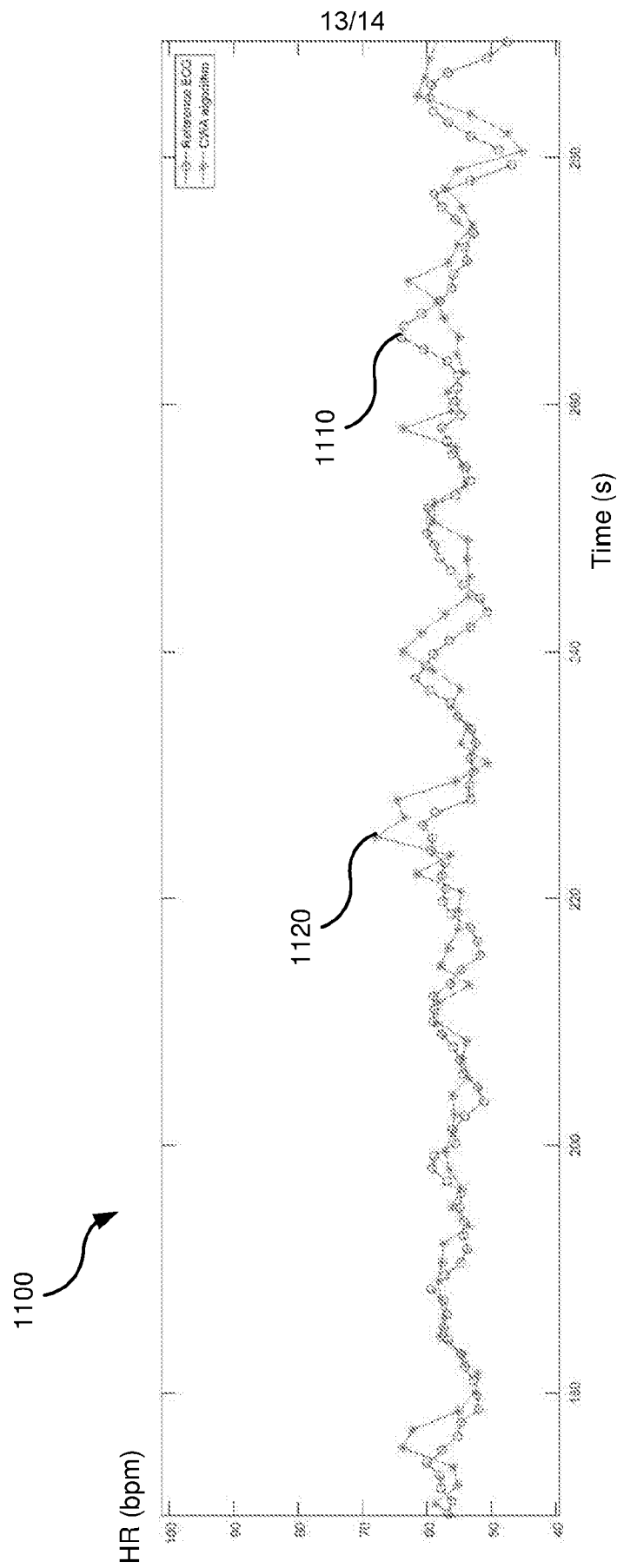


FIG. 11

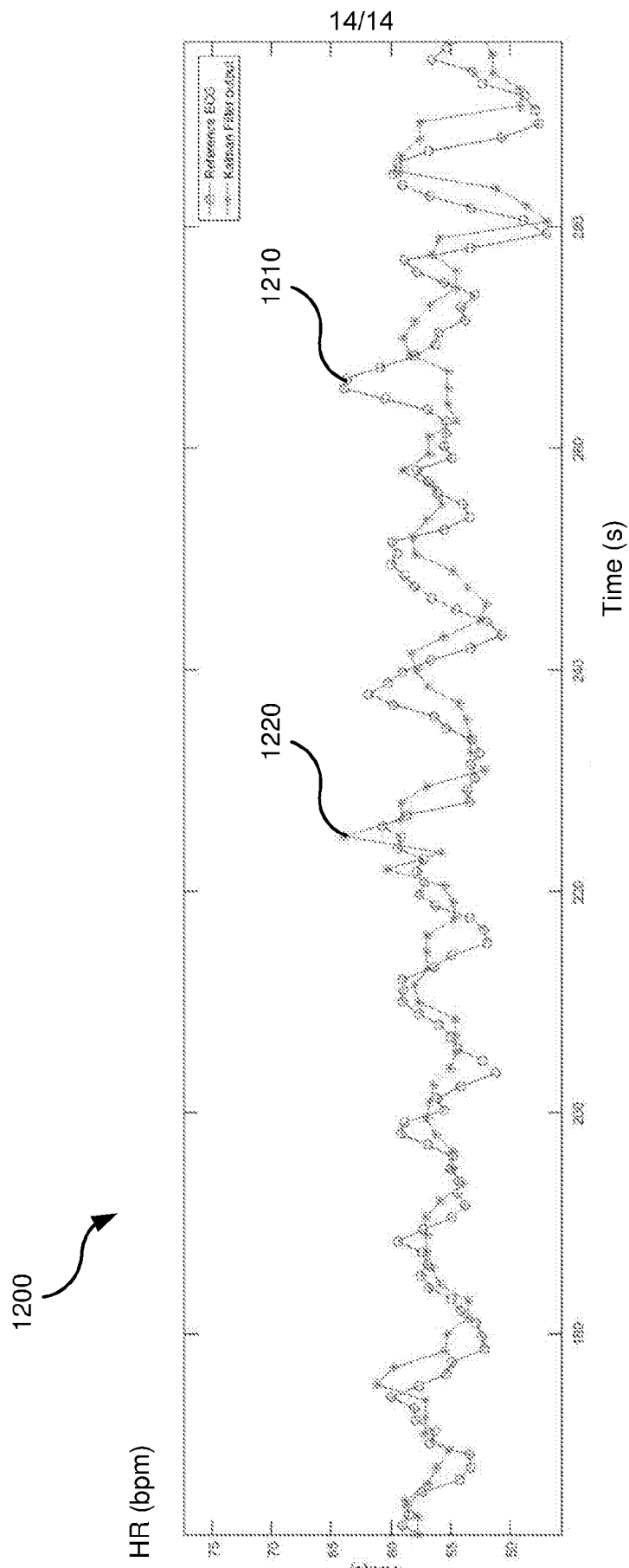


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2017/050859

A. CLASSIFICATION OF SUBJECT MATTER A61B 5/11 (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, Google, Google Patents, Google Scholar, ESPACENET. IPC & CPC: A61B5/11, A61B5/1102, A61B5/6813, A61M16, A61B5/6814, A61B2562/0219. Keywords: Ballistocardiography, gyroscope, Hilbert, kalman, cpap, mask, patient interface and similar terms in various combinations.		
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 "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 14 December 2017	Date of mailing of the international search report 14 December 2017	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustalia.gov.au	Authorised officer Cromwel Flores AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61399359661	

INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/AU2017/050859
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2015/036925 A1 (MURATA MANUFACTURING CO. LTD.) 19 March 2015 See whole document. Especially: Fig 4; page 7 lines 19-29; page 8 line 24-page 9 line 12; claims 11, 36.	1, 3, 4, 6, 7, 10, 11, 13, 17-30
X	US 2016/0007935 A1 (HERNADEZ et al.) 14 January 2016 See whole document. Especially: [0058]-[0065]; [0088]-[0094]; [0113]; [0116]-[0122].	1-30
A	WO 2008/135985 A1 (EARLYSENSE LTD) 13 November 2008	
A	WO 2015/107374 A1 (IMPERIAL INNOVATIONS LIMITED) 23 July 2015	
A	WO 2016/033121 A1 (GEORGIA TECH RESEARCH CORPORATION) 03 March 2016	
A	WO 2010/145009 A1 (HEART FORCE MEDICAL INC.) 23 December 2010	
A	INAN et al. Ballistocardiography and Seismocardiography: A Review of Recent Advances. IEEE Journal of Biomedical and Health Informatics. 7 October 2014 pages 1414 - 1427 https://doi.org/10.1109/JBHI.2014.2361732 Retrieved on 6 December 2017	

Form PCT/ISA/210 (fifth sheet) (July 2009)

INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/AU2017/050859	
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 2015/036925 A1	19 March 2015	WO 2015036925 A1	19 Mar 2015
		CA 2922364 A1	19 Mar 2015
		CN 105530866 A	27 Apr 2016
		EP 3043712 A1	20 Jul 2016
		FI 20135924 A	14 Mar 2015
		FI 126008 B	31 May 2016
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		KR 20160074482 A	28 Jun 2016
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		JP 2016195774 A	24 Nov 2016
		US 2011046498 A1	24 Feb 2011
		US 8585607 B2	19 Nov 2013
		US 2014046209 A1	13 Feb 2014
		US 8734360 B2	27 May 2014
		US 2011112442 A1	12 May 2011
		US 8821418 B2	02 Sep 2014
		US 2013267791 A1	10 Oct 2013
		US 8882684 B2	11 Nov 2014
		US 2014350351 A1	27 Nov 2014
		US 8998830 B2	07 Apr 2015
		US 2016093196 A1	31 Mar 2016
		US 9449493 B2	20 Sep 2016

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INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/AU2017/050859	
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 2012132211 A1	31 May 2012
		US 2012253142 A1	04 Oct 2012
		US 2014005502 A1	02 Jan 2014
		US 2014371635 A1	18 Dec 2014
		US 2015164438 A1	18 Jun 2015
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		WO 2012077113 A2	14 Jun 2012
		WO 2013150523 A1	10 Oct 2013
		WO 2015008285 A1	22 Jan 2015
WO 2015/107374 A1	23 July 2015	WO 2015107374 A1	23 Jul 2015
		EP 3096686 A1	30 Nov 2016
		US 2016338648 A1	24 Nov 2016
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		WO 2010/145009 A1	23 Dec 2010
		CA 2765358 A1	23 Dec 2010
		CN 102458237 A	16 May 2012
		EP 2442710 A1	25 Apr 2012
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End of Annex			
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