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(54) Title of the Invention: **Physiological sensing**
 Abstract Title: **Manually optimising sensor position based on the quality of a generated physiological respiration signal.**

(57) A device 201 which improves the quality of determined physiological signals by instructing a user to correctly position the device in a location where the best physiological measurements can be taken. The physiological parameter is respiration or alternatively may be heart rate or tidal volume. A motion sensor is used to take the physiological measurements and may be a camera (306, fig. 3), an accelerometer or a gyroscope. A signal is generated from the measurements and compared with a predetermined threshold or pattern to determine the quality. Dependent on the signal quality feedback is provided on where the sensor device should be placed in contact with a user's body 202. Preferably, feedback is in the form of directions to a user on where to hold the device. However, other feedback forms may be audio including vocal cues, video, visual via a display (302, fig. 3), haptic or optical.

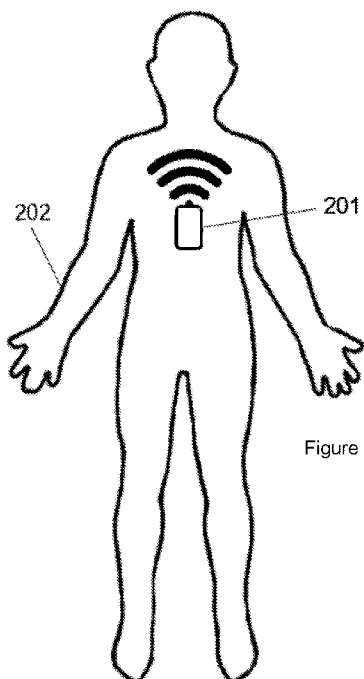


Figure 2

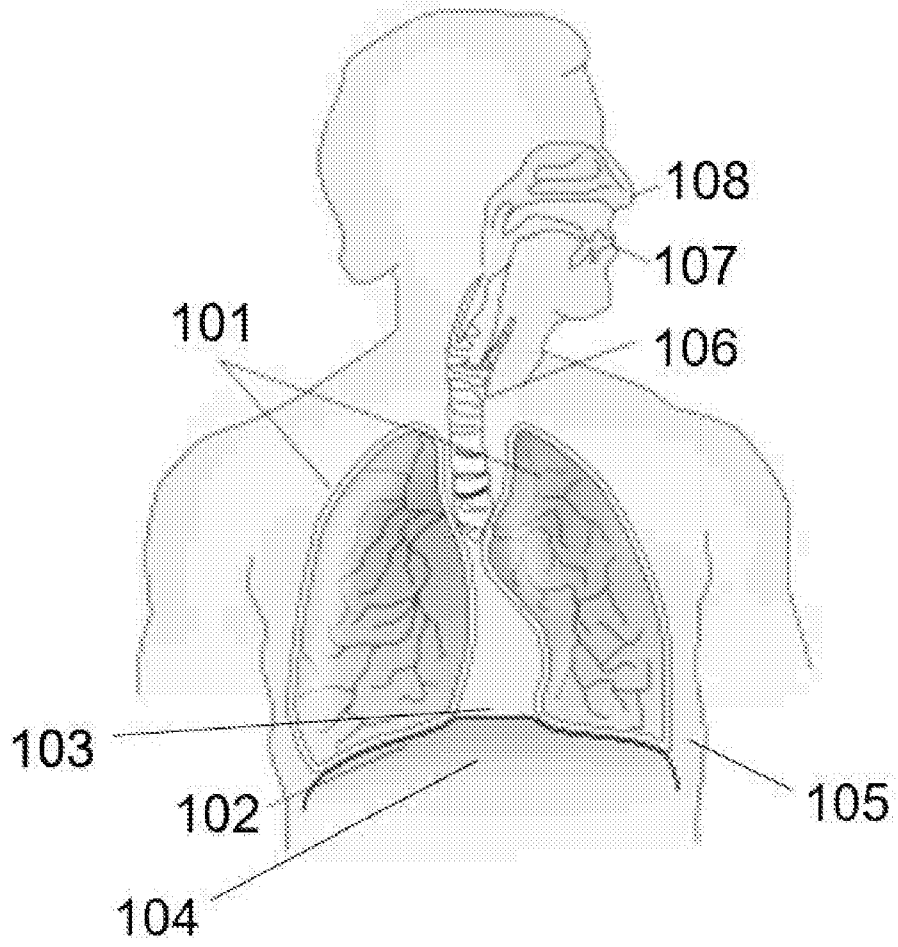


Figure 1

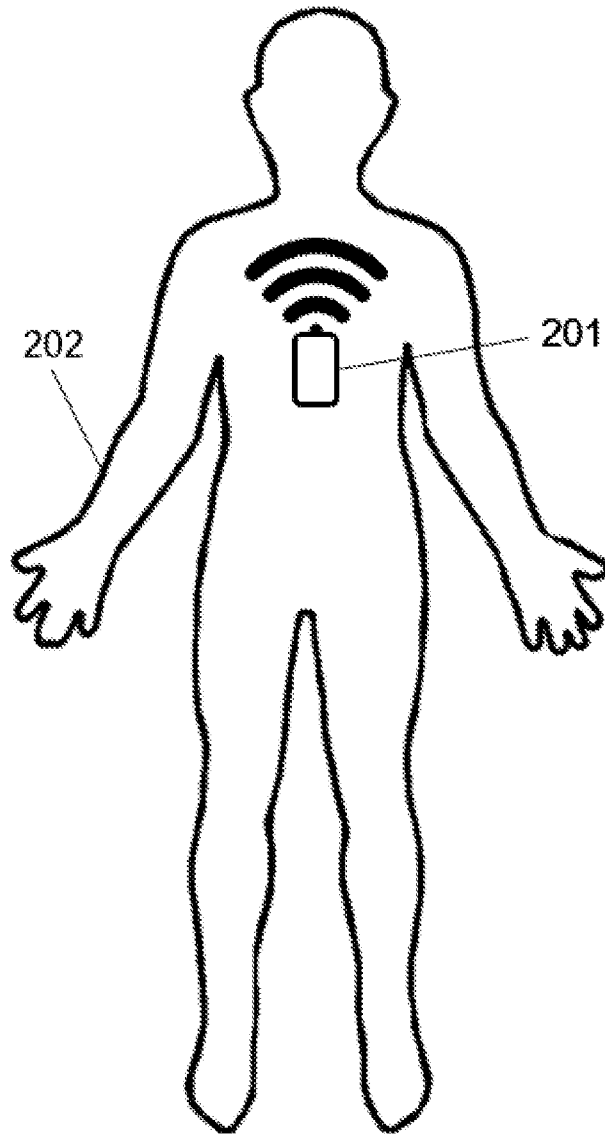


Figure 2

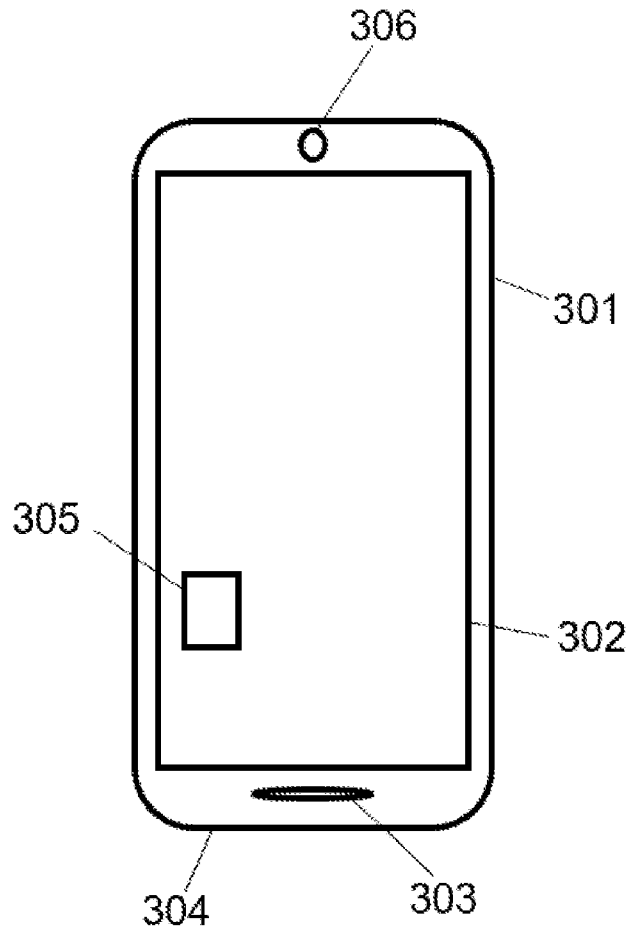


Figure 3

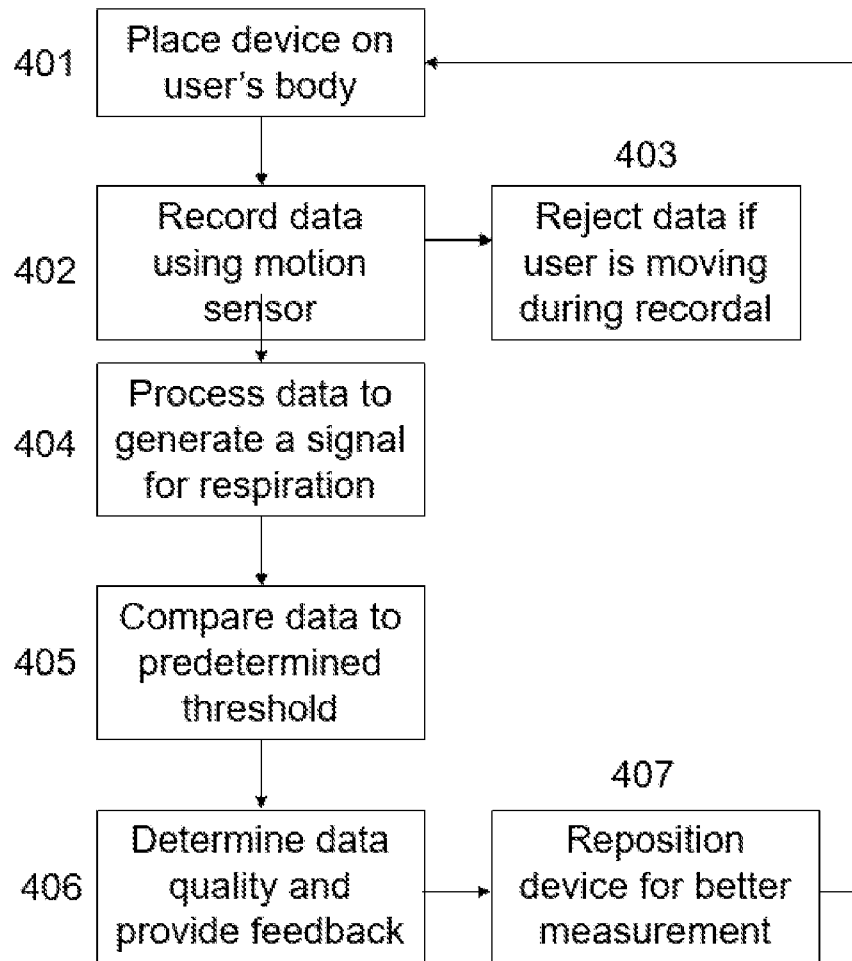


Figure 4

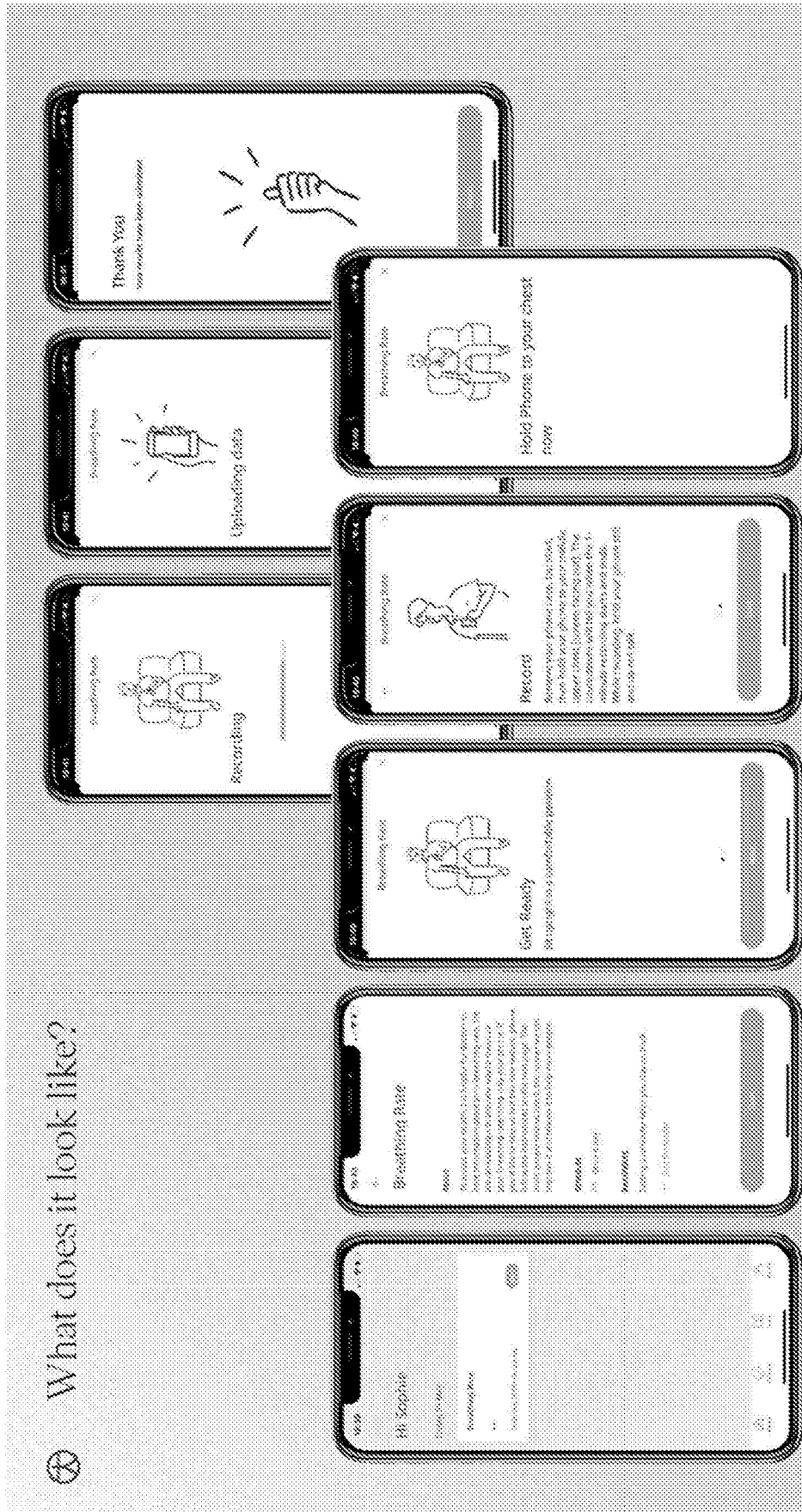


Figure 5

PHYSIOLOGICAL SENSING

This invention relates to a device for sensing a physiological parameter such as respiration rate or heart rate. The parameter may be sensed through a mechanism
5 that can provide data when a sensing device is in contact with a user, for example a motion sensor.

The respiratory system of the body facilitates gas exchange. The lungs are the primary organs of the respiratory system. The mouth and nose form the entrance to the
10 airways of the body. The airways include a series of branching tubes, which become narrower, shorter and more numerous as they penetrate deeper into the lung. The primary function of the lung is gas exchange, allowing oxygen to move from the air into the venous blood and carbon dioxide to move out. The trachea divides into right and left main bronchi; the bronchi make up the conducting airways and do not take
15 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.

The process of respiration is divided into two distinct phases: inhalation (inspiration)
20 and exhalation (expiration). During inhalation, the diaphragm contracts and pulls downward while the muscles between the ribs contract and pull upward. This increases the size of the thoracic cavity, thus the pressure inside decreases and air rushes in as a result to fill the lungs. During exhalation, the diaphragm relaxes and the volume of the thoracic cavity decreases, increasing the pressure within it. As a
25 result, the lungs contract and air is expelled.

The main muscles involved in breathing are located in the chest and abdomen. The diaphragm and, to a lesser extent, the intercostal muscles drive respiration during quiet breathing. Additional muscles are typically only used under conditions of high
30 metabolic demand or respiratory dysfunction such as an asthma attack. The diaphragm is a thin, dome-shaped muscle that separates the abdominal cavity from the thoracic cavity. During inhalation, the diaphragm contracts and its centre moves

downwards, compressing the abdominal cavity and raising the ribs upward and outward to expand the thoracic cavity. When the diaphragm relaxes, elastic recoil of the thoracic wall causes the thoracic cavity to contract, forcing air out of the lungs and returning to its dome-shape. The intercostal muscles are attached between the ribs and are involved in controlling the width of the rib cage.

A range of respiratory disorders exist. Certain disorders may be characterised by particular events, e.g. apnoeas, hypopnoeas, and hyperpnoeas. Such disorders may be detected and monitored by measuring the respiration rate. Some disorders are associated with an increased or reduced rate of breathing, by an irregular breathing rate or by events such as coughing that disrupt a subject's normal breathing pattern. Some disorders are associated with characteristic noises generated by the respiratory system: for example wheezing or crepitations.

There exists a number of measurement techniques for sensing breathing and calculating respiration rate. An example of such a technique is the use of a belt incorporating a piezoelectric film worn around the chest or abdomen where the breathing of the subject is detected in accordance with a tensile force acting on the belt. Such a configuration in which a belt is worn by the subject, carries the risk that the subject will feel significant discomfort and that the subject's breathing will be affected such that the subject will find it more difficult to breathe while wearing the belt. A further disadvantage of the technique is the limited access of the average household to such equipment.

In an alternative example, a sensor is attached to the chest or abdomen of the subject and the breathing of the subject is detected by detecting changes in the curvature of the chest or abdomen. A problem with this configuration is that the sensitivity with which abdominal breathing is detected is poor when the sensor is attached to the chest of the subject and the sensitivity with which chest breathing is detected is poor when the sensor is attached to the abdomen of the subject. There is also the problem that the breathing sensing device must be large in order to detect changes in curvature.

In a further example, sensors which deform in response to the motion of breathing are adhered to a body. The sensor is configured to detect the breathing of the subject by detecting relative positional changes between the region corresponding to the xiphisternum and the epigastrium. This technique is similarly inaccessible to the majority of users and requires precise positioning of sensors in order to achieve measurements that can be used to generate a reading of respiration rate.

There is a need for an improved method of determining breathing or other physiological characteristics using a device which is readily available to a majority of users. A solution to the issue of positioning such a device to detect a suitable signal is also required. It is an object of the present invention to provide a respiration measurement device capable of providing feedback to a user about the optimal position of a detector for measurement.

The physiological characteristic may be a characteristic of a thoracic organ, such as heart rate or respiration rate. The physiological characteristic may be a cyclic physical characteristic.

According to a first aspect there is provided a device for determining a physiological characteristic using a motion sensor, the device being configured to process data from the motion sensor when the device is in contact with a user's body to generate a signal representative of the physical characteristic of the user; the device being configured to compare the processed data with a predetermined threshold or pattern to determine the quality thereof and to, in dependence on that comparison, provide feedback for indicating to the user that the position of the device should be varied to improve the quality of the determined respiration rate.

The device may provide feedback contemporaneously with the measurement of the motion of breathing for assisting the placement of the device to detect a signal representing the respiration rate of the user.

The device may be configured to generate directions to a user to hold the device on their body while the signal is detected.

5 The device may be configured to reject detected signals if the comparison of the data indicate that the body of a user is moving during the detection process.

10 The device may detect the physiological condition respiration rate and the respiration rate is determined by detecting the movement during a plurality of inhalation and exhalation cycles and dividing the number of inhalations or exhalations detected during the period by the period.

The at least one motion sensor may be an accelerometer, gyroscope, magnetometer, camera or CCD.

15 The device may provide feedback as audio feedback. The audio feedback may be synchronised with the detected inhalation and exhalation of the user. The audio feedback may include vocal cues provided by the device to ask the user to adjust or re-try the device position. The audio feedback may indicate the quality of the generated signal.

20

The device may provide feedback as video feedback. The device may be configured to display a visual representation of the body together with one or more indicia indicating the position of the device on the body and an idealised position for detection.

25 The device may provide feedback for positioning the device as haptic stimuli.

The device may provide feedback for positioning the device as optical feedback.

30 The device may be configured to provide feedback for indicating that the device is correctly positioned for measurement.

According to an embodiment, there is a method of using a device, wherein the device is held against the body of the first user by a person different from the first user.

5 The present invention will now be described by way of example with reference to the accompanying drawings. In the drawings:

Figure 1 shows a schematic of the human respiratory system.

10 Figure 2 shows a physiological sensor device during use on a person.

Figure 3 shows an exemplary device.

Figure 4 shows an overview of the feedback process during positioning of the device.

15 Figure 5 shows an exemplary visual display on a smartphone of an app to implement the sensing and adjustment.

DETAILED DESCRIPTION

20 The following description is presented to enable any person skilled in the art to make and use the invention, and is provided in the context of a particular application. Various modifications to the disclosed embodiments will be readily apparent to those skilled in the art.

25 The general principles defined herein may be applied to other embodiments and applications, without departing from the spirit and scope of the present invention. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

30

The human respiratory system is shown in figure 1. The mouth 107 and nose 108 form the airways which connect to the trachea 106 which branches to meet the lungs

101. The sternum is situated in front of the lungs, with the xiphisternum 103 in the centre of the body. The lungs are supported by the diaphragm 102 which is proximal to the epigastrium 104. Surrounding the lungs at the side of the body are the intercostal muscles 105.

5

Figure 2 shows a device 201 is positioned in contact with a user's body 202. The device is placed on the user's chest. Alternatively, the device may be held by a user in contact with a body. Conveniently the device may be positioned so as to be adjacent the user's sternum. More generally the device may be positioned so as to be adjacent
10 any part of the user's ribcage or abdomen or adjacent any part of the user's upper chest. Conveniently the device is positioned on the front of the user's body. Conveniently the device is positioned on a part of the user's body that moves as the user breathes in and out. The user may be seated, or prone or standing. Thus, when a major face of a detecting device is placed against the user's chest, that major face
15 may be substantially vertical (e.g. within 20 degrees of vertical) or substantially horizontal (e.g. within 20 degrees of horizontal), or it may be in another orientation. The device may be directly in contact with the user's body (i.e. in contact with the user's skin) or indirectly in contact with the user's body by virtue of being pressed to the user's clothing. The device may be held against a user by that user themselves
20 or by another person. The latter option may be convenient when the first user is, for example, an infant.

Figure 3 shows a device suitable as device 201. The device may be a cellular phone, smartphone or tablet, it may alternatively be a device dedicated for monitoring
25 breathing. In this example the device 301 of figure 3 is a smartphone. The device 301 has a screen 302 for presenting visual feedback to a user. The screen may be an LCD, OLED, LED, plasma or other display; it may be a capacitive or resistive touchscreen that allows a user to input data. The device has one or more sensors 305 present. Each sensor may be a motion sensor, specifically a gyroscope, accelerometer, magnetometer, piezoelectric material, acoustic detector or equivalent.
30 For example, the device may comprise a multi-axis accelerometer, a magnetometer and a gyroscopic motion sensor. A camera 306 may be provided in the device 301,

the camera may be used to detect motion. The device has a microphone 303 which is capable of recording audio inputs. The device further has a speaker 304 which can emit sound, as illustrated in figure 2. The device may be configured to connect to an external audio output such as headphones. The device comprises a processor
5 coupled to the screen, sensor(s) 305, camera, microphone and speaker. The processor is also coupled to a transceiver comprised in the device. That may, for example be a transceiver for a wireless protocol. The device comprises a memory that stores in non-transient form code executable by the processor to cause it to perform the functions described herein.

10

An advantage of the device being a smartphone is that most of the population have access to such a device, meaning that users would be able to measure their respiration in domestic settings and at regular intervals to monitor health.

15 As will be described in more detail below, the processor is capable of:

1. receiving data from the sensor(s) 305 and/or the microphone;
2. analysing that data to attempt to detect artefacts representative of cyclical motion, optionally of cyclical motion whose magnitude and/or frequency and/or variability are in a predetermined range;

20

3. comparing the result of that detection step with a predetermined set of thresholds or patterns so as to assess whether the data is of a quality associated with those thresholds or patterns; and

25

4. in dependence on that comparison step, causing one or more the speaker and the display to provide feedback to the user for encouraging the user to move the device on their body so as to improve the quality of the sensed data.

The quality of the detected signal as a means of capturing data about a periodic physiological function may be estimated in any suitable way. For example, in a first step, the magnitude of rotation or translation over segments of the captured data can
30 be measured and compared, to check if the device is being held sufficiently still. In a second step, an estimated frequency of the physiological function may be determined. This may be determined from historic data for typical individuals or by spectral analysis

of the captured data to determine one or more dominant frequencies in the data. In a third step an autocorrelation operation may be performed in which the correlation is determined between (i) the captured data and (ii) a copy of the captured data delayed by the period of the frequency determined in the first step. The third step may be repeated for a set of frequencies. The quality of the captured data may be represented by the uniformity and frequency of the highest values of these autocorrelations.

The output of the detection step may represent a measurement of a physiological parameter of the user such as their respiration or heart rate. That output may be stored, presented to the user and/or transmitted to a remote location for further analysis.

The device may estimate a user's tidal volume. This may be estimated from one or more of the following inputs: (i) information regarding the status of the user: for example their age, height and/or weight; (ii) an estimate of the user's respiration rate formed in the manner described herein; (iii) information collected by a microphone sensor of the device representing the sound of the user breathing. This data may be combined using a suitable algorithm, for example one derived from machine learning, to estimate the user's tidal volume.

The device comprises a rigid or semi-rigid case which holds the other components described above. The case may be of a cuboid form. Conveniently at least one face of the cuboid has an area greater than 30cm^2 . Conveniently two opposite faces of the cuboid have areas that are more than 5 times those of the other faces. These features can facilitate the device being placed flat on a user's chest. When the device has a display the display may be on such a major face.

When the device is in position on the user's chest it may be held against the chest by gravity, or the user may press the device against their chest using their hand. The user may be seated or standing. Alternatively the user may lie with their chest on the device, preferably over a resilient substrate such as a mattress, or the user may lie on their back with the device placed on their chest facing upwards.

To initiate sensing, the user may operate a user interface of the device (e.g. its touchscreen or using voice input) to activate a sensing mode. That sensing mode may be provided by an app or application running on the device. The app may cause the device to display instructions to the user to position the device on their chest.

When the sensing mode is initiated, the processor receives data from its inputs (e.g. the motion sensor(s) and/or the microphone) and analyses it to attempt to detect artefacts in the data that are associated with a generally cyclical pattern characteristic of the motion of the chest during respiration. This may, for example, be done by filtering the received data and applying a Fourier transform to it, or applying autocorrelation analysis, or using wavelet functions, or through a trained machine learning algorithm. It may be expected that a given physiological mechanism will have a frequency within known bounds. For example, including cases where an individual is unwell or is tested after exercising, a breathing rate might be in the range from 4 to 50 per minute and a heart rate might be in the range from 20 to 250 per minute. The processor may filter the data to reject data associated with frequencies outside a predetermined band.

When the processor is processing data from the motion sensor(s), it may be configured to identify motion data associated with the rising and falling of the user's chest due to breathing or to the user's heart rate. For that reason, it may give a greater weight to motion data representing translation having a component perpendicular to a major face of the device or rotation having a component in a major plane of the device than to other motions.

The processor may combine data from the motion sensor(s) and the microphone by attributing a greater degree of quality to a sensed frequency if the same frequency is detected from the data from the motion sensor(s) and the data from the microphone.

The processor attributes a quality level to the estimation of a frequency from the sensed data. This may be done in any of a number of ways. The quality may be

dependent on any one or more of: (i) the magnitude of a cyclical signal detected in motion and/or audio data, with a greater magnitude indicating greater quality; (ii) the level of agreement in the frequencies of cyclical signals detected from two different sensors (e.g. a motion sensor and the microphone); (iii) the extent to which the strongest detected frequency has a greater strength than the sum of the remaining detected frequencies; (iv) the variability of a cyclical signal over the period of measurement, with a lower variability indicating greater quality and (v) the overall movement of the device (in terms of acceleration, translation or rotation), with too great a movement representing lower quality. A predetermined algorithm may be used to combine any two or more metrics to form an overall quality. A predetermined algorithm may combine metrics which have the highest computed confidence. The algorithm may vary or use different processing steps depending on the specific device or motion sensor used. For example, a specific brand of smartphone or motion sensor may be calibrated differently or produce a different format or resolution or frequency of data. A single selected quality or the overall quality can then be compared with a predetermined threshold or pattern to provide an indication of whether the sensed data is adequate.

If the sensed data is determined not to be adequate then the device provides the user with an output to encourage the user to move the device on their body or hold a more still position. The sensed data may be inadequate for a number of reasons: holding the device in the wrong position, moving around during the measurement, holding the device in the wrong orientation, usage of a case around the device that muffles the signals, wearing too much heavy clothing, or not holding the device in position for long enough. That output may be on the device's display. More preferably, the output is an audio output from the device's loudspeaker. This has the advantage that it can be better appreciated by the user when the device is positioned on their chest. An audio feedback output may take any convenient form. In one example it may be a beep, tone, series of tones, melody or other predetermined non-verbal noise. In another example it may be a verbal output, for example a phrase asking the user to move the device or make other adjustments. In another example it may be a sound generated in dependence on the sensed data. That sound may be a synthesised breathing or

heartbeat sound that varies at the same frequency as a cyclical signal that has been detected in the sensed data. The synthesised breathing or heartbeat sound may be in phase with the cyclical signal. The pitch and/or volume of the synthesised sound may be dependent on the quality the sensed data has been estimated to have.

5

Optionally, the device may receive inputs about the user such as age, height, weight, and pre-existing conditions in order to calibrate the expected output.

The device is configured to provide feedback to the user for indicating to the user that the position of the device should be varied to improve the quality of the measurement. Such feedback may be provided as at least one of audio, visual or haptic feedback. The audio feedback may be verbal directions such as “move the phone towards your head”, or sound effects representative of proximity to an optimal position such a beeps of varying pitch, frequency or intensity. There may also be feedback to indicate to the user that the phone is positioned correctly. Such feedback may be by any suitable mechanism: for example audio, haptic or visual.

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The device may be held by a first user on the chest of a second user. In this case we expect the first user to respond to feedback about phone placement. For example, a parent or carer measuring respiratory rate of a child or a baby, or a relative or carer measuring respiratory rate of an older person.

20

The accurate measurement of respiratory or heart rate may require a period of measurement such as 30 seconds or 1 minute. However, the device may be configured to provide feedback to the user more frequently, for example after 10 seconds or 20 seconds of measurement. The device may be further configured to provide live and real-time feedback to the user during the course of the measurement, by constantly sampling data quality from preceding windows of 10 seconds or 20 seconds.

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The device contains a processor or processing unit that may be configured to distinguish outputs from the sensor caused by the breathing of a user from other

movements, other vibrations caused by sounds. Such signal processing may use a frequency filter to distinguish between frequency components, allowing a plurality of signals to be detected simultaneously. The signal caused by the user's breathing may be distinguished from sound signals and the two signals can be compared to detect abnormal breathing such as an asthma attack.

Figure 4 shows an exemplary process flow for an embodiment of the device. The device is first positioned on a user at step 401. Data is recorded using the motion sensor at step 402, this data is then either rejected at step 403 or processed to generate a signal for separation at step 404. The generated signal is compared with a predetermined threshold to determine the quality of the data at step 405. Dependent on the quality of the data, feedback is provided about the measurement position of the device at step 406, the feedback prompts the user to reposition the device for better measurement at step 407, returning to step 401 to iterate the process again.

The device may be used to detect any one or more of respiration rate, heart rate, tidal volume and other cyclical physiological events or characteristics.

The device may provide a general instruction to a user, indicating for example that the device is to be moved. Alternatively it may provide more specific instructions: for example to move the device to a different position, for the user to stop moving their body, for the user to hold the device still for a longer period, for the user to not talk or for the user to attempt again without coughs, sneezes or sudden movements.

An example of an app on a device configured to perform the assessment is shown in figure 5. Various screens of a visual output are shown which provide instructions to a user.

Applications of the device include assessment of health conditions and breath training for relaxation. For example, an indicator of a possible health condition in a subject or an increase in severity of a health condition in a subject may be an increase in the breathing rate of the subject.

The applicant hereby discloses in isolation each individual feature described herein and any combination of two or more such features, to the extent that such features or combinations are capable of being carried out based on the present specification as a whole in the light of the common general knowledge of a person skilled in the art, 5 irrespective of whether such features or combinations of features solve any problems disclosed herein, and without limitation to the scope of the claims. The applicant indicates that aspects of the present invention may consist of any such individual feature or combination of features. In view of the foregoing description it will be evident 10 to a person skilled in the art that various modifications may be made within the scope of the invention.

CLAIMS

1. A device for determining a physiological characteristic using a motion sensor, the device being configured to process data from the motion sensor when the device
5 is in contact with a user's body to generate a signal representative of the physical characteristic of the user; the device being configured to compare the processed data with a predetermined threshold or pattern to determine the quality thereof and to, in dependence on that comparison, provide feedback for indicating to the user that the position of the device should be varied to improve the quality of the determined
10 respiration rate.
2. The device of claim 1 wherein the feedback is provided contemporaneously with the measurement of the motion of breathing for assisting the placement of the device to detect a signal representing the respiration rate of the user.
15
3. The device of claim 1 or 2 wherein the device is configured to generate directions to a user to hold the device on their body while the signal is detected.
4. The device of any preceding claim wherein device is configured to reject
20 detected signals if the comparison of the data indicate that the body of a user is moving during the detection process.
5. The device of any preceding claim wherein the physiological condition is respiration rate and the respiration rate is determined by detecting the movement
25 during a plurality of inhalation and exhalation cycles and dividing the number of inhalations or exhalations detected during the period by the period.
6. The device of any preceding claim wherein the at least one motion sensor is an accelerometer.
30
7. The device of any preceding claim wherein the at least one motion sensor is a gyroscope.

8. The device of any preceding claim wherein the at least one motion sensor is a camera or CCD.
- 5 9. The device of any preceding claim wherein the feedback is provided as audio feedback.
10. The device of claim 9 wherein the audio feedback is synchronised with the detected inhalation and exhalation of the user.
- 10 11. The device of claim 9 or 10 wherein the audio feedback includes vocal cues provided by the device to ask the user to adjust or re-try the device position.
12. The device of any of claims 9 to 11 wherein the audio feedback indicates the quality of the generated signal.
- 15 13. The device of any preceding claim wherein the feedback is provided as video feedback.
- 20 14. The device of any preceding claim wherein the device is configured to display a visual representation of the body together with one or more indicia indicating the position of the device on the body and an idealised position for detection.
15. The device of any preceding claim wherein the feedback for positioning the device is provided as haptic stimuli.
- 25 16. The device of any preceding claim wherein the feedback for positioning the device is provided as optical feedback.
- 30 17. The device of any preceding claim wherein the device is configured to provide feedback for indicating that the device is correctly positioned for measurement.

18. A method of using a device as claimed in any preceding claim, wherein the device is held against the body of the first user by a person different from the first user.



Application No: GB2008043.8

Examiner: Dr Gemma Candy

Claims searched: 1-18

Date of search: 26 November 2020

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X,E	1-3, 6-13, 15-17	WO2020/162741 A1 (SAFI-HARB) See especially abstract, ref 242, 244 and 246 in fig. 2 , pg. 6 lines 18-21, pg. 15 line 21.
X	1-18	US2017/0010670 A1 (TANAKA et al) See especially abstract, fig. 7, and paragraphs [0038], [0070-0073], [0078-0079].
X	1-7, 9-18	EP3430980 A1 (HILGERS et al) See especially paragraphs [0035-0037], [0042], [0078], [0085-0087].
X	1, 3, 7, 9-18	US2017/0120107 A1 (WISBEY) See especially fig. 11, and paragraphs [0076-0077]
X	1-7, 9-18	US2016/0278647 A1 (VOGEL et al) See especially abstract, figs 1-9, and paragraphs [0026-0031], [0034-0036].
X	1-7, 9-18	US2010/0298899 A1 (DONNELLY et al) See especially paragraphs [0028], [0035-0037], [0039], [0045], [0049], [0060].
X	1-7, 9-13, 15-18	WO2017/081284 A1 (GREGG et al) See especially abstract, and pg. 6 lines 6-19, pg. 7 lines 20-25, pg. 8 lines 29-32.

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X :

Worldwide search of patent documents classified in the following areas of the IPC

A61B

The following online and other databases have been used in the preparation of this search report



WPI, EPODOC

International Classification:

Subclass	Subgroup	Valid From
A61B	0005/00	01/01/2006
A61B	0005/024	01/01/2006
A61B	0005/113	01/01/2006