



- (51) International Patent Classification:
A61B 5/00 (2006.01) *A61M 16/00* (2006.01)
- (21) International Application Number:
PCT/GB2014/000184
- (22) International Filing Date:
14 May 2014 (14.05.2014)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
1310826.1 18 June 2013 (18.06.2013) GB
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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, DK, DM,

DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, 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, 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).

Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- of inventorship (Rule 4.17(iv))

[Continued on next page]

(54) Title: RESPIRATORY THERAPY APPARATUS AND METHODS

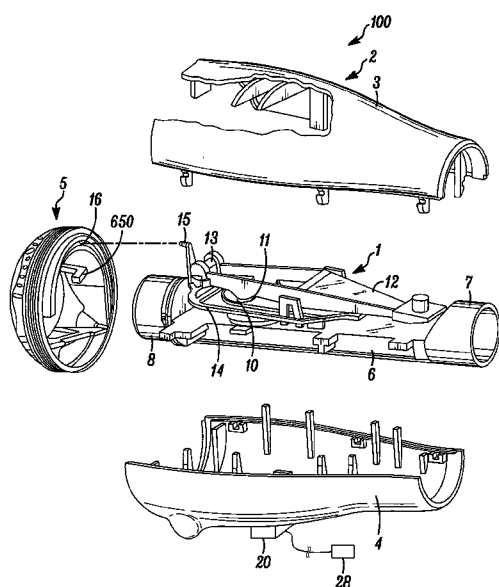


FIG. 1

(57) Abstract: A vibratory PEP respiratory therapy device (100) includes a valve element (11) on a rocker arm (12) that opens and closes an opening (10) during exhalation through the apparatus. An accelerometer (20) including a piezoelectric beam (22) supported at one end (23) is mounted on the outside of the housing (2) of the device to respond to vibration transmitted through the housing caused by oscillating movement of the rocker arm (12). The output of the accelerometer (20) is supplied to a circuit (28), (29) that determines when the device (100) is used and the duration and quality of use of the device.



Published:

— *with international search report (Art. 21(3))*

RESPIRATORY THERAPY APPARATUS AND METHODS

This invention relates to respiratory therapy apparatus of the kind including a device having a structure and a movable member mounted with the structure that is caused to oscillate by the action of breathing through the device.

The invention is also concerned with methods of evaluating patient use of respiratory therapy apparatus.

Positive expiratory pressure (PEP) apparatus, that is, apparatus that presents a resistance to expiration through the device, are now widely used to help treat patients suffering from a range of respiratory impairments, such as chronic obstructive pulmonary disease, bronchitis, cystic fibrosis and atelectasis. More recently, such apparatus that provide an alternating resistance to flow have been found to be particularly effective. One example of such apparatus is sold under the trade mark Acapella (a registered trade mark of Smiths Medical) by Smiths Medical and is described in US6581598, US6776159, US7059324 and US7699054. Other vibratory respiratory therapy apparatus is available, such as "Quake" manufactured by Thayer, "AeroPEP" manufactured by Monaghan, "TheraPEP" manufactured by Smiths Medical and "IPV Percussionator" manufactured by Percussionaire Corp. Alternative apparatus such as "CoughAssist" manufactured by Philips is also available. Respiratory therapy apparatus can instead provide an alternating resistance to flow during inhalation.

To be effective these apparatus must be used regularly at prescribed intervals. In the case of chronic diseases, the patient needs to use the apparatus daily for the rest of his life in order to maintain continuous relief.

Although these apparatus can be very effective, users often neglect to use the apparatus regularly at the prescribed frequency. It is very difficult to maintain a record of use of the apparatus, especially when the patient is using it at home. The clinician often does not know whether

deterioration in a patient's condition is because he has failed to use the apparatus as prescribed or whether other factors are the cause.

It is an object of the present invention to provide alternative respiratory therapy apparatus.

According to one aspect of the present invention there is provided a respiratory therapy apparatus of the above-specified kind, characterised in that the apparatus includes a sensor mounted with the structure and responsive to vibration transmitted through the structure caused by the oscillating movement of the movable member to provide a signal indicative of use of the device.

The structure preferably includes an outer housing of the device. The sensor is preferably mounted on the outside of the outer housing. The sensor may include an accelerometer. The sensor may include a beam including a piezoelectric element, the beam being supported at one end such that vibration transmitted through the structure causes the beam to flex and produces a change of output from the piezoelectric element. The beam preferably supports a mass towards an opposite end. The device may include a store for storing the output of the sensor. The apparatus may be arranged to provide an output representation indicative of one or more of the following: when the apparatus is used, the duration of use and the quality of use of the apparatus. The apparatus may include a valve element on a rocker arm that opens and closes an opening during exhalation through the apparatus. The device may be a vibratory PEP therapy device, the device being arranged to produce an oscillating resistance to expiration through the device.

According to another aspect of the present invention there is provide a method of evaluating use of a respiratory therapy device including a structure and a movable member mounted on the structure that is caused to oscillate by the action of breathing through the device, characterised in that the method includes the step of monitoring vibration transmitted through the structure of the device.

The method preferably includes the step of storing an indication of periods of sensed vibration. The method may include the step of determining frequencies of vibration.

According to a further aspect of the present invention there is provided apparatus for use in a method according to the above other aspect of the present invention.

Apparatus including a vibratory PEP device and its method of use according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is an exploded view of the apparatus;

Figure 2 is a perspective view of the interior of the sensor;

Figure 3 illustrates an alternative form of sensor;

Figure 4A illustrates the output from a single expiration;

Figure 4B illustrates the output over a treatment cycle of multiple breaths; and

Figure 4C illustrates use of the apparatus over a week.

With reference first to Figure 1, the respiratory therapy device 100 comprises a rocker assembly 1 contained within an outer housing 2 provided by an upper part 3 and a lower part 4 of substantially semi-cylindrical shape. The device is completed by an adjustable dial 5 of circular section. The outer housing 2 contains an air flow tube 6 with a breathing inlet 7 at one end and an inspiratory inlet 8 at the opposite end including a one-way valve (not shown) that allows air to flow into the air flow tube but prevents air flowing out through the inspiratory inlet. The air flow tube 6 has

an outlet opening 10 with a non-linear profile that is opened and closed by a conical valve element 11 mounted on a rocker arm 12 pivoted midway along its length about a transverse axis. The air flow tube 6 and housing 2 provide a structure with which the rocker arm 12 is mounted. At its far end, remote from the breathing inlet 7, the rocker arm 12 carries an iron pin 13 that interacts with the magnetic field produced by a permanent magnet (not visible) mounted on an adjustable support frame 14. The magnet arrangement is such that, when the patient is not breathing through the device, the far end of the rocker arm 12 is held down such that its valve element 11 is also held down in sealing engagement with the outlet opening 10. A cam follower projection 15 at one end of the support frame 14 locates in a cam slot 16 in the dial 5 such that, by rotating the dial, the support frame 14, with its magnet, can be moved up or down to alter the strength of the magnetic field interacting with the iron pin 13. The dial 5 enables the frequency of operation and the resistance to flow of air through the device to be adjusted for maximum therapeutic benefit to the user.

When the patient inhales through the breathing inlet 7 air is drawn through the inspiratory inlet 8 and along the air flow tube 6 to the breathing inlet. When the patient exhales, the one-way valve in the inspiratory inlet 8 closes, preventing any air flowing out along this path. Instead, the expiratory pressure is applied to the underside of the valve element 11 on the rocker arm 12 causing it to be lifted up out of the opening 10 against the magnetic attraction, thereby allowing air to flow out to atmosphere. The opening 10 has a non-linear profile, which causes the effective discharge area to increase as the far end of the rocker arm 12 lifts, thereby allowing the arm to fall back down and close the opening. As long as the user keeps applying sufficient expiratory pressure, the rocker arm 12 will rise and fall repeatedly as the opening 10 is opened and closed, causing a vibratory, alternating or oscillating interruption to expiratory breath flow through the device. Further information about the construction and operation of the device can be found in US6581598, the contents of which are hereby incorporated into the present application.

As so far described, the device is conventional.

The apparatus of the present invention includes the device 100 described above and a sensor 20 attached to the structure of the device. In particular, the sensor 20 is attached to the external surface of the housing 2. Although it would be possible to mount the sensor 20 internally within the housing 2, mounting the sensor externally avoids the need to provide electrical access within the

device. The sensor 20 is responsive to vibration transmitted through the structure of the device caused by parts of the rocker arm 12 contacting other parts of the device as it oscillates up and down in see-saw fashion. The sensor 20 could be of any conventional kind responsive to vibration, such as an accelerometer. Preferably, however, the sensor 20 includes a piezoelectric element 21 of the kind shown in Figure 2. The piezoelectric element 21 is a model MiniSense 100NM or MiniSense 100 available from Measurement Specialities, although other piezoelectric sensors could be used. It includes a thin, bendable rectangular beam 22 that is itself of a piezoelectric material or includes a piezoelectric material bonded to a supporting substrate. The beam 22 is supported at one end 23 in cantilever fashion by two pillars 24, which also act as electrodes to provide electrical connection to the element 21, and hold the beam spaced above and parallel to a circuit board 25. The opposite, free end 26 of the beam 22 supports a small mass 27 so that any acceleration in the vertical plane causes the free end of the beam to flex up or down. This flexing of the piezoelectric element 21 causes a charge or voltage to be produced across the output electrodes 24. Vibration transmitted through the structure provided by the air flow tube 6 and the housing 2 causes the piezoelectric element 21 to vibrate at a frequency and with an amplitude dependent on the frequency and magnitude (forcefulness) of oscillation of the rocker arm 12.

The sensor element 21 has a good linearity and dynamic range. The mass 27 may be modified to vary the frequency response and sensitivity. The element 21 may be used to detect either continuous or impulsive vibration or impacts. For excitation frequencies below its resonant frequency, the piezoelectric element 21 produces a linear output governed by the "baseline" sensitivity. The sensitivity at resonance is significantly higher. Impacts containing high frequency components will excite the resonance frequency. The ability of the sensor element 21 to detect low frequency motion is strongly influenced by the external electrical circuit.

The output of the piezoelectric element 21 is supplied to a circuit 29 on the board 25, which is preferably an LDTC MiniSense 100 Analog PCB. The circuit 29 includes a low-power operational amplifier, comparator, DC/DC converter, store and passive components used in signal conditioning and has an adjustable gain. The sensor 20 may itself include processing means or this may be provided externally in a unit 28. In particular, the processing is arranged to convert the output from the piezoelectric element 21 into usable parameters by suitable statistical treatment, such as time-domain or frequency-domain analysis. Conventional signal processing using fast fourier transformation, correlation analysis, finite impulse filters and the like may be used. The sensor 20 also

includes a memory for recording the output and may also include a display for providing information to the patient, such as average frequency of vibration, day and time of the therapy sessions, duration of the therapy sessions and an indication of the quality of the exhalation breaths, representing the average pressure or flow as derived from the amplitude of the sensed vibration. The board also has an output socket 120, such as for a USB connector or may have a wireless output, such as using the Bluetooth radio frequency protocol.

Instead of being mounted on a circuit board, the piezoelectric element 21' could be encapsulated in a protective capsule 30 as shown in Figure 3. The capsule 30 includes little or no processing circuitry but has a connector 31 by which connection can be made to a remote circuit at which the processing and storage can be carried out.

The typical output from the piezoelectric element 21 during a single exhalation is shown in Figure 4A where the output rises along an approximate square wave with a superimposed alternating signal as the oscillation of the rocker arm 12 becomes more forceful during the exhalation. When the user has exhausted his exhalation breath the rocker arm 12 reverts to a stationary state with the outlet opening 10 closed. When this happens the output of the piezoelectric element 21 rapidly falls.

Figure 4B shows a succession of breaths during a single therapy session.

Figure 4C shows seven traces, one for each day of the week, with marks indicating when therapy sessions have taken place.

It will be appreciated that there are many different ways in which information obtained from the sensor can be represented so that it is provided to the user and clinician in the most useful manner.

Apparatus of the present invention can be used with any conventional respiratory therapy apparatus that produces a vibration. The therapy apparatus may be combined with other treatments such as nebulisation or the administration of aerosol medication.

The present invention enables existing, conventional therapy apparatus that is known and trusted by the user and clinician to be readily modified to provide useful data about use of the apparatus. In this way, the user can be made more aware of how well he is complying with the prescribed therapy programme and can modify his use of the apparatus accordingly to achieve maximum benefit. The clinician is also able to check patient compliance so that he can identify whether any deterioration in a patient's condition is due to lack of compliance or if alternative treatment is needed.

CLAIMS

1. Respiratory therapy apparatus including a device (100) having a structure (2) and a movable member (12) mounted with the structure that is caused to oscillate by the action of breathing through the device, characterised in that the apparatus includes a sensor (20) mounted with the structure (2) and responsive to vibration transmitted through the structure caused by the oscillating movement of the movable member (12) to provide a signal indicative of use of the device.
2. Respiratory therapy apparatus according to Claim 1, characterised in that the structure includes an outer housing (2) of the device (100).
3. Respiratory therapy apparatus according to Claim 2, characterised in that the sensor (20) is mounted on the outside of the outer housing (2).
4. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the sensor (20) includes an accelerometer (21).
5. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the sensor (20) includes a beam (22) including a piezoelectric element (21), and that the beam (22) is supported at one end such that vibration transmitted through the structure (2) causes the beam (22) to flex and produces a change of output from the piezoelectric element (21).
6. Respiratory therapy apparatus according to Claim 5, characterised in that the beam (22) supports a mass (27) towards an opposite end (26).
7. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the apparatus includes a store (29) for storing the output of the sensor (20).

8. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the apparatus is arranged to provide an output representation indicative of one or more of the following: when the apparatus is used, the duration of use and the quality of use of the apparatus.
9. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that apparatus includes a valve element (11) on a rocker arm (12) that opens and closes an opening (10) during exhalation through the apparatus.
10. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that device (100) is a vibratory PEP therapy device, and that the device is arranged to produce an oscillating resistance to expiration through the device.
11. A method of evaluating use of a respiratory therapy device (100) including a structure (2) and a movable member (12) mounted on the structure that is caused to oscillate by the action of breathing through the device, characterised in that the method includes the step of monitoring vibration transmitted through the structure (2) of the device.
12. A method according to Claim 11, characterised in that the method includes the step of storing an indication of periods of sensed vibration.
13. A method according to Claim 11 or 12, characterised in that the method includes the step of determining frequencies of vibration.
14. Apparatus for use in a method according to any one of Claims 11 to 13.

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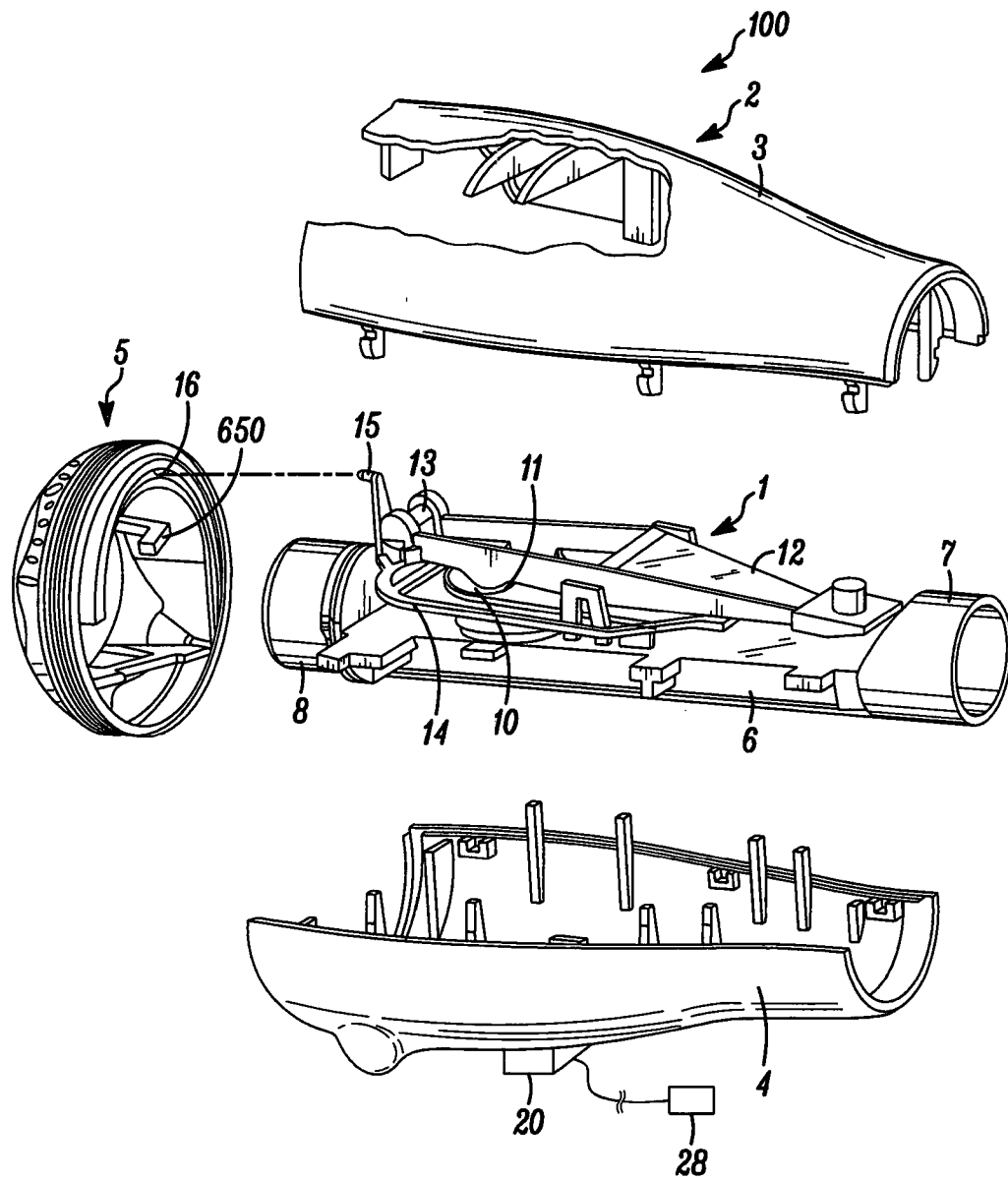


FIG. 1

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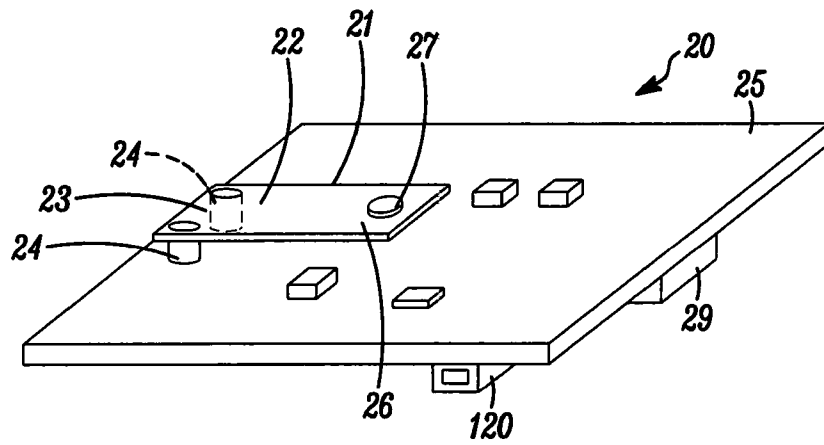


FIG. 2

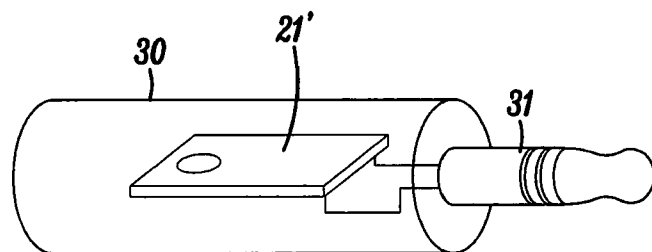


FIG. 3

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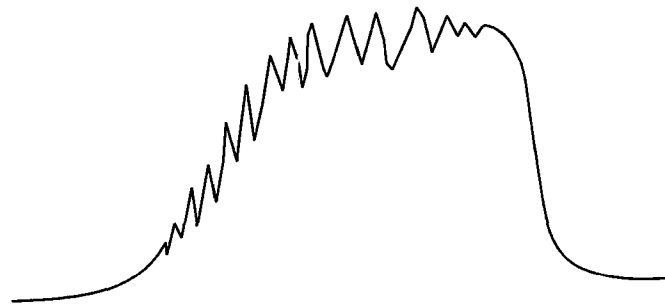


FIG. 4A

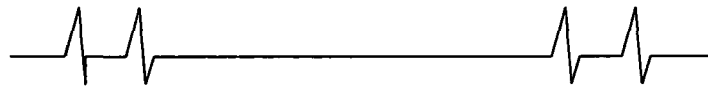


FIG. 4B

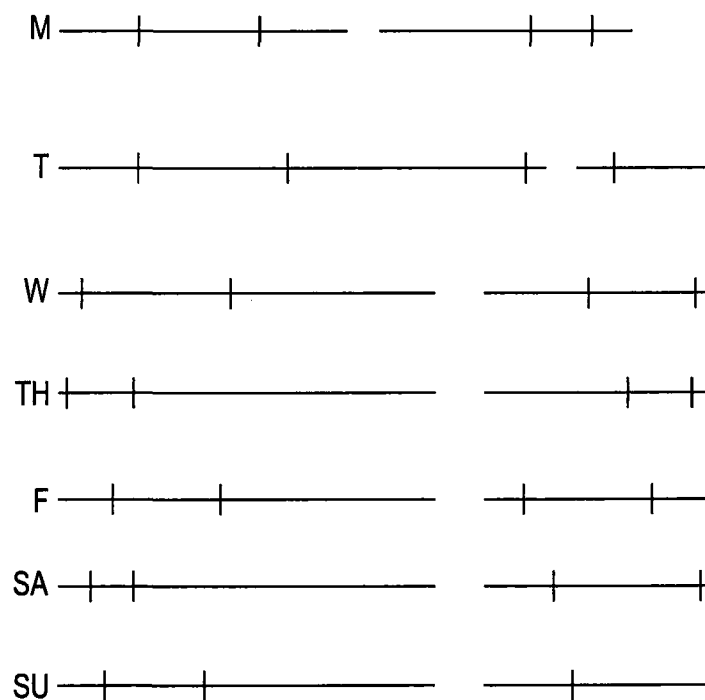


FIG. 4C

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2014/000184

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00 A61M16/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61M

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/023039 A1 (ISHIZAKI TAKAYUKI [JP] ET AL) 1 February 2007 (2007-02-01)	1-4,7,8, 10,14
Y	the whole document	5,6,9
X	EP 1 900 387 A1 (INVACARE CORP [US]) 19 March 2008 (2008-03-19)	1-3,7,8, 10
Y	the whole document	9
X	US 2004/187871 A1 (KIMMEL STEVEN A [US] ET AL) 30 September 2004 (2004-09-30)	1-3,7,8, 10
Y	the whole document	9
X	WO 2012/085756 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; LAURA LAPOINT MANUEL [US]; O'CONN) 28 June 2012 (2012-06-28)	1-3,7,8, 10
Y	the whole document	9
	----- -/-	



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

10 July 2014

Date of mailing of the international search report

21/07/2014

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2014/000184

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

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

1. ☒ Claims Nos.: 11-13
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

Remark on Protest

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 11-13

Claims 11 to 13 refers to a method for evaluating use of a respiratory therapy device. In contrast to an apparatus or product claim, in case of a method claim commencing with such words as "A method for ..." the part "for evaluating use of a respiratory therapy" should not be understood as meaning that the method is merely suitable therefore, but rather the feature in the "for"-part is defining one of the method steps of the claimed method. Consequently, the use of the respiratory therapy device is to be understood as an explicit inextricably interrelated method step of said method. Thus the claimed method qualifies as therapeutic, according to Rule 39(iv) PCT.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/000184

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2014/000184

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			WO 2012104513 A2	09-08-2012
