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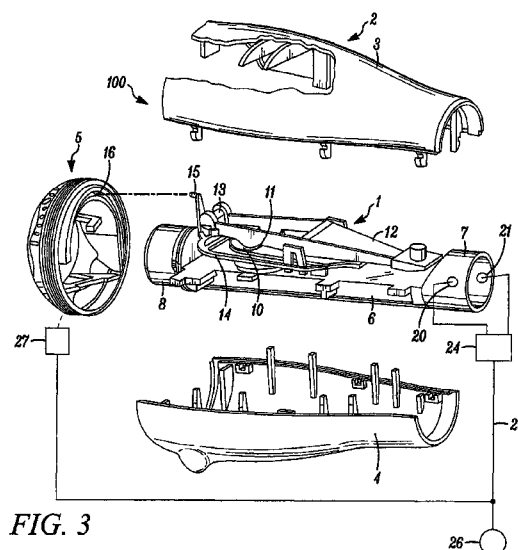
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- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- of inventorship (Rule 4.17(iv))

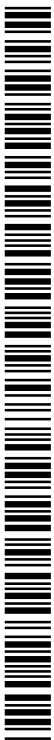
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(54) Title: RESPIRATORY THERAPY APPARATUS



(57) Abstract: Respiratory therapy apparatus includes an oscillating expiratory therapy device (100) and pressure and flow sensors (20 and 21) in the patient inlet (7) connected to supply signals to a processor (24). The processor (24) includes artificial intelligence software to correlate the output signals with prescribed values and control a feedback device (26) that prompts the patient accordingly to adjust use of the device as necessary. The feedback device (26) may be of a visual, audible or tangible kind. The processor (24) may also automatically adjust a setting dial (5) of the therapy device (100) by means of an actuator (27).



RESPIRATORY THERAPY APPARATUS

This invention relates to respiratory therapy apparatus of the kind including a device having a mechanism arranged to produce an oscillating resistance to breathing through the device, the therapy device having a plurality of different operation settings.

Patients with respiratory system diseases (such as asthma, COPD, cystic fibrosis or the like) may suffer from hyper-secretion of mucus as a prominent pathophysiological feature. Moreover, those patients with hyper-secretion often also have impaired mucus transport. This imbalance between mucus transport and secretion results in mucus retention in the respiratory system.

Vibratory respiratory positive expiratory pressure (V-PEP) or oscillatory PEP (OPEP) devices are modern devices for applying chest physiotherapy. These devices apply chest physiotherapy by providing an alternating resistance to flow and 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, "IPV Percussionator" manufactured by Percussionaire Corp, and the "Flutter" and "Lung Flute" devices, amongst others. These devices are used by patients who suffer from mucus hyper-secretions and retention to help them clear the secretions from their lungs. The Acapella O-PEP device combines the principles of low-frequency oscillation and positive expiratory pressure by employing a counterweighted lever and magnet to produce oscillatory positive pressures during expiration. This generated oscillating positive pressure works by mechanically reducing the viscoelasticity of the sputum by breaking down the bonds of mucus macromolecules which, in turn, enhances mucociliary clearance.

More recently it has been proposed to indicate the effectiveness of this therapy by placing a vibration sensor on the patient's chest, as described in PCT/GB2014/000220. In PCT/GB2014/000184 it is proposed to mount a vibration sensor on the casing of the therapy

device to provide a signal indicative of use of the device. In PCT/GB2014/000177 it is proposed to use an external audio sensor, such as in a mobile phone, to monitor use of the device. These more recent proposals are mainly concerned with monitoring patient compliance.

The appropriate use of the O-PEP devices is critically dependent on the mechanical parameters of the pressure produced by the device, that is, the mean value of PEP, the frequency and amplitude of the generated oscillation. Typically, clinicians or respiratory therapists are responsible for selecting the appropriate airway clearance therapy for a particular patient ("The Value of Conducting Laboratory Investigations on Airway Clearance Devices," 2008; Respiratory Therapist Series, 1985; California Thoracic Society, 2006). They are also responsible for optimizing the operation of O-PEP devices to achieve the desired therapy goals (Hristara-Papadopoulou et al., 2008; California Thoracic Society, 2006; Myers, 2007).

These mechanical parameters, however, are dependent on the patient flow rate and the setting of the O-PEP device. Patients suffering from mucus hypersecretion and retention have various degrees of flow limitation. It has been observed that the mechanical parameters of the generated pressure vary across the spectrum of flow ranges, as shown in Figures 1A, 1B and 1C. The air flow/volume exhalation curve for patients using O-PEP devices is non-linear, as shown in Figure 2. This, and the lack of any feedback to the patient makes it very difficult for the patient to maintain the flow rates prescribed by the clinician or respiratory therapist for the appropriate period.

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

According to the present invention there is provided respiratory therapy apparatus including a respiratory therapy device of the above-specified kind, characterised in that the apparatus includes pressure and flow sensors responsive to gas pressure and flow produced by the patient, and a processor connected to receive output signals of the pressure and flow sensors and arranged correlate the output signals from the pressure and flow sensors with

prescribed values, that the processor is arranged to provide an output to a feedback device in accordance with the extent to which the signals correlate with the prescribed values, and that the feedback device is arranged to be perceived by the patient to prompt him to adjust his use of the therapy device.

The device may include an actuator controlled by the output of the processor to adjust the position of a member arranged to control the setting of the therapy device. The member arranged to control the setting of the therapy device may be a rotatable dial. The feedback device may be arranged to produce a visual feedback and or alternatively an audible feedback and or alternatively a tangible feedback. The pressure and flow sensors may be located in the region of the breathing inlet of the therapy device. The processor preferably includes artificial intelligence software. The therapy device may include a rocker arm arranged to open and close an outlet during exhalation. The processor preferably is arranged to record the settings used for each therapy session.

Respiratory therapy apparatus according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

- Figures 1A to 1C illustrate the mechanical behaviour of a prior art O-PEP devices over a range of flow rates;
- Figure 2 illustrates the exhalation curve of prior art O-PEP devices;
- Figure 3 illustrates the apparatus of the present invention; and
- Figure 4 is a flow chart showing operation of the apparatus.

With reference first to Figure 3, the apparatus includes an "Acapella" O-PEP device 100 comprising 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 100 is completed by an adjustable dial 5 of circular section. The rocker assembly 1 includes an air flow tube 6 with a breathing inlet 7 which may include or be coupled to a mouthpiece. An

inspiratory inlet 8 at the opposite end includes a one-way valve (not shown) that allows air to flow into the air flow tube 6 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. Other O-PEP devices may have different setting arrangements for adjusting operation of the device and may be graduated in other ways, such as in frequency.

When the patient inhales through the breathing inlet or mouthpiece 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 apparatus additionally includes a pressure sensor 20 and a flow sensor 21 mounted in the region of the breathing inlet 7 of the device 100 so that they are exposed to expiratory air flow upstream of the oscillating mechanism of the device. The pressure and flow sensors need not be separate, as shown, but could be incorporated into a single unit providing that information about both pressure and flow can be extracted from the output signals. The outputs from the sensors 20 and 21 are supplied to a processing unit 24 either by a wire connection (as shown) or by a wireless connection, such as with the Bluetooth protocol radio frequency transmission. The processing unit 24 may be mounted on the housing 2 of the O-PEP device 100 or remotely. The processing unit 24 preferably includes artificial intelligence software such as VisualState, visSIM or LabView software.

The processing unit 24 produces a first output via a feedback channel 25 to a feedback device 26 that provides the user with feedback as to his use of the device. The feedback may confirm correct use or indicate incorrect use and how this might be mitigated, such as by breathing more forcefully or less forcefully, breathing for a longer or shorter period or altering the setting of the device. The feedback device could be of various different kinds, such as a visual device (typically a flashing light, a light of varying colour or intensity, or a moving needle or other element), an audible device (such as a buzzer, or a speaker via which spoken instructions are given to the user), or a tangible device (such as a vibrator or a braille tactile display) or any combination of these. The processing unit 24 may optionally also produce an output signal automatically to alter the setting of the device 100 such as to a settings adjustment actuator 27, which may incorporate a stepper motor, solenoid or other actuator to rotate the dial 5 or otherwise alter the position of a settings member.

Operation of the apparatus will now be described with reference also to Figure 4. Initially, when the apparatus is first turned on, the processing unit 24 provides an output to the feedback device to recommend a setting (as indicated by box A) for the adjustable dial 5. Alternatively, where the apparatus includes an adjustment device 27 it may automatically set the adjustable dial 5 to the prescribed setting. The user then starts breathing through the device 100 so that flow and pressure data are collected, as indicated by box B. The software in the processing unit 24 now determines whether the flow and pressure are higher than

required for the present setting, as indicated in box C. If the answer is Yes, the device gives the user feedback to change to a more appropriate setting or it automatically makes this change of setting, as indicated in box D. If the flow, however is not too high, the next step, as indicated in box E, is to determine if the flow is lower than required for the present setting. If the answer is Yes, the user is again given feedback or an automatic setting change is made, as shown in box D. If the flow is not higher than required, that is, the setting is correct for the user's breathing, the process returns to box B. In this way, use of the apparatus is continuously monitored and adjusted as the user changes the way in which he uses the O-PEP device. Furthermore, the user is given confidence that he is achieving maximum benefit from the respiratory therapy.

The present invention can be used to ensure that the apparatus is always at the most appropriate setting to achieve maximum therapeutic benefit for the user.

The apparatus preferably records in the processor the settings used for each therapy session since this could give an indication to the clinician of changes in the patient's clinical state that might require alternative or additional treatment.

CLAIMS

1. Respiratory therapy apparatus of the kind including a device (100) having a mechanism (1) arranged to produce an oscillating resistance to breathing through the device, the therapy device having a plurality of different operation settings, characterised in that the apparatus includes pressure and flow sensors (20 and 21) responsive to gas pressure and flow produced by the patient, and a processor (24) connected to receive output signals of the pressure and flow sensors and arranged to correlate the output signals from the pressure and flow sensors (20 and 21) with prescribed values, that the processor (24) is arranged to provide an output to a feedback device (26) in accordance with the extent to which the signals correlate with the prescribed values, and that the feedback device (26) is arranged to be perceived by the patient to prompt him to adjust his use of the therapy device (100).
2. Respiratory therapy apparatus according to Claim 1, characterised in that apparatus includes an actuator (27) controlled by the output of the processor (24) to adjust the position of a member (5) arranged to control the setting of the therapy device (100).
3. Respiratory therapy apparatus according to Claim 1, characterised in that the member arranged to control the setting of the therapy device (100) is a rotatable dial (5).
4. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the feedback device (26) is arranged to produce a visual feedback.
5. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the feedback device (26) is arranged to produce an audible feedback.
6. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the feedback device (26) is arranged to produce a tangible feedback.

7. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the pressure and flow sensors (20 and 21) are located in the region of a breathing inlet (7) of the therapy device (100).
8. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the processor (24) includes artificial intelligence software.
9. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the therapy device includes a rocker arm (12) arranged to open and close an outlet (10) during exhalation.
10. Respiratory therapy apparatus according to any one of the preceding claims, characterised in that the processor (24) is arranged to record the settings used for each therapy session.

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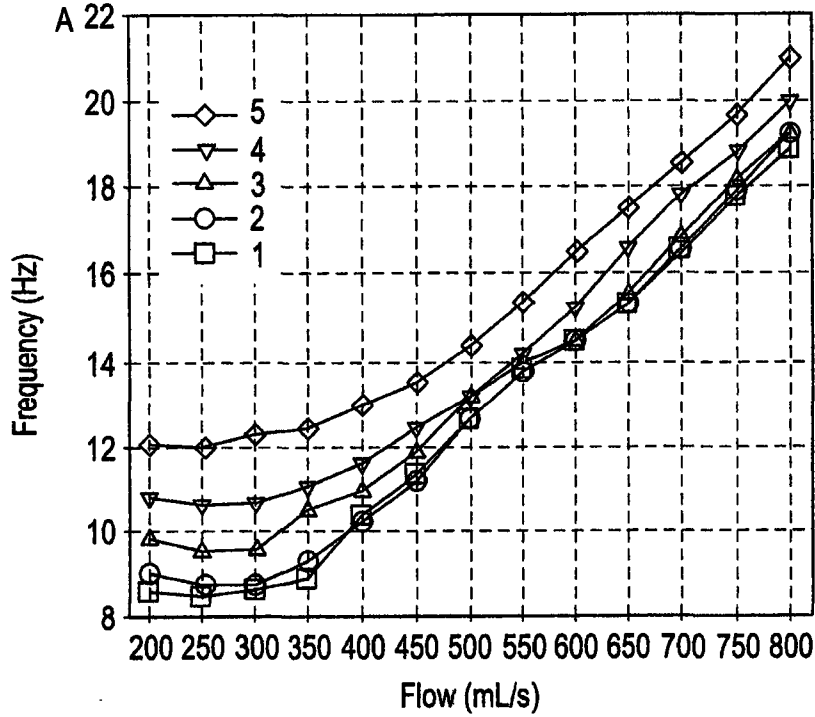


FIG. 1A

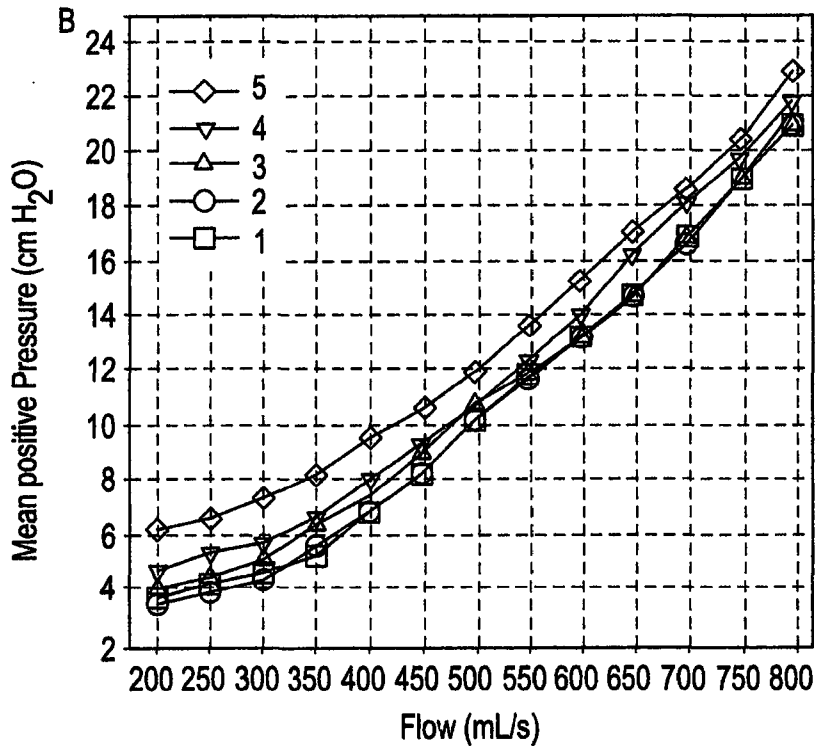


FIG. 1B

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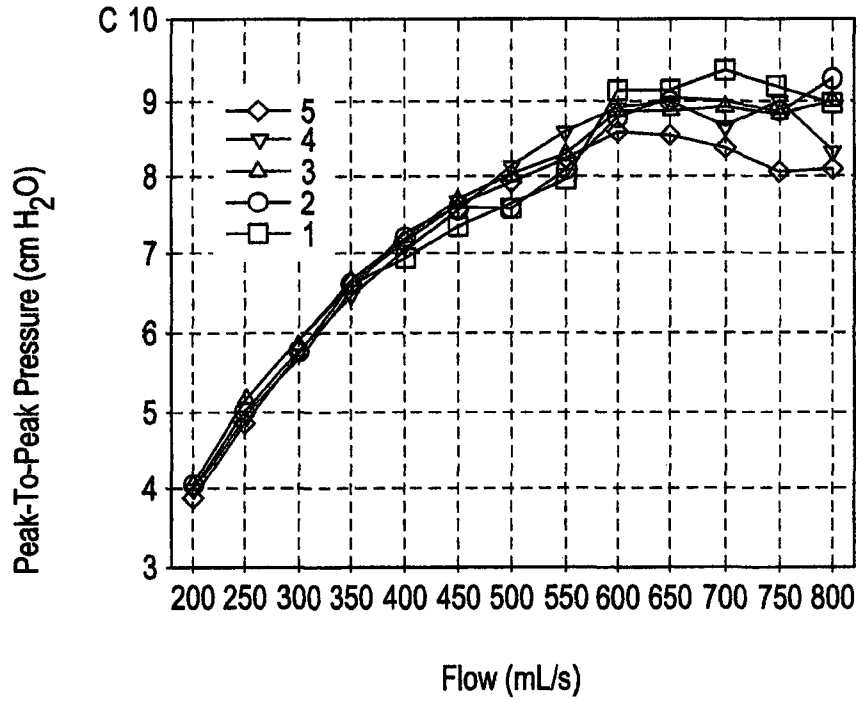


FIG. 1C

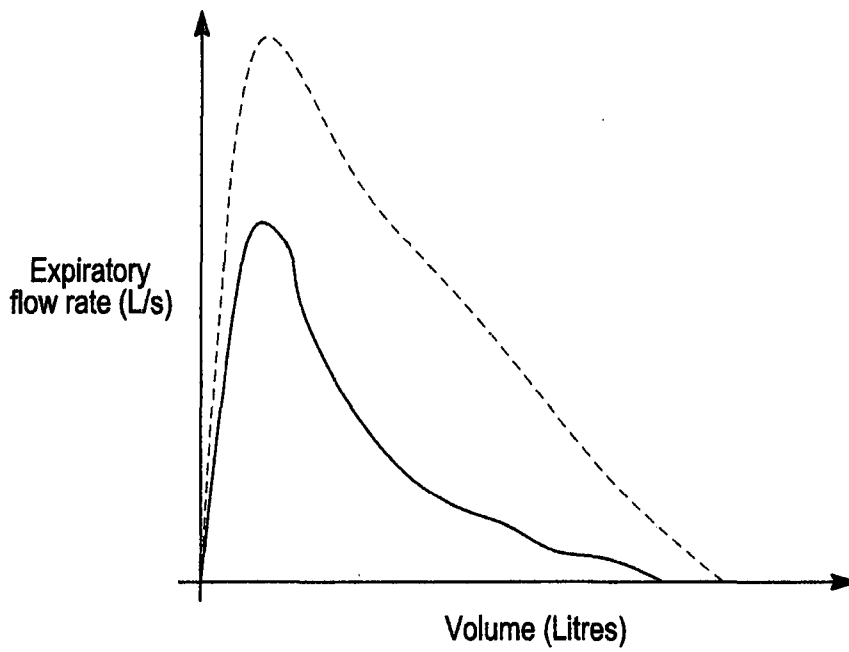


FIG. 2

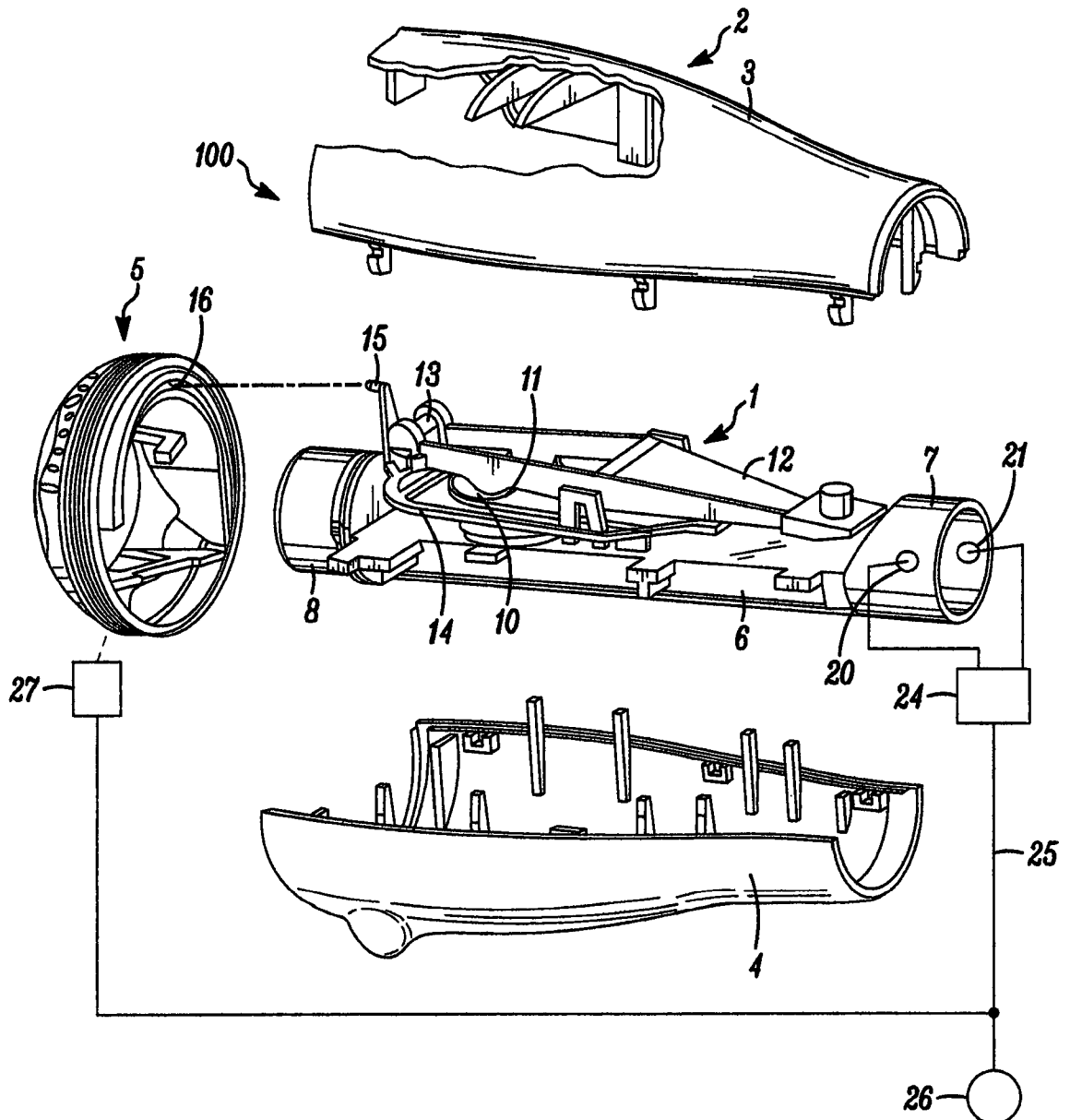


FIG. 3

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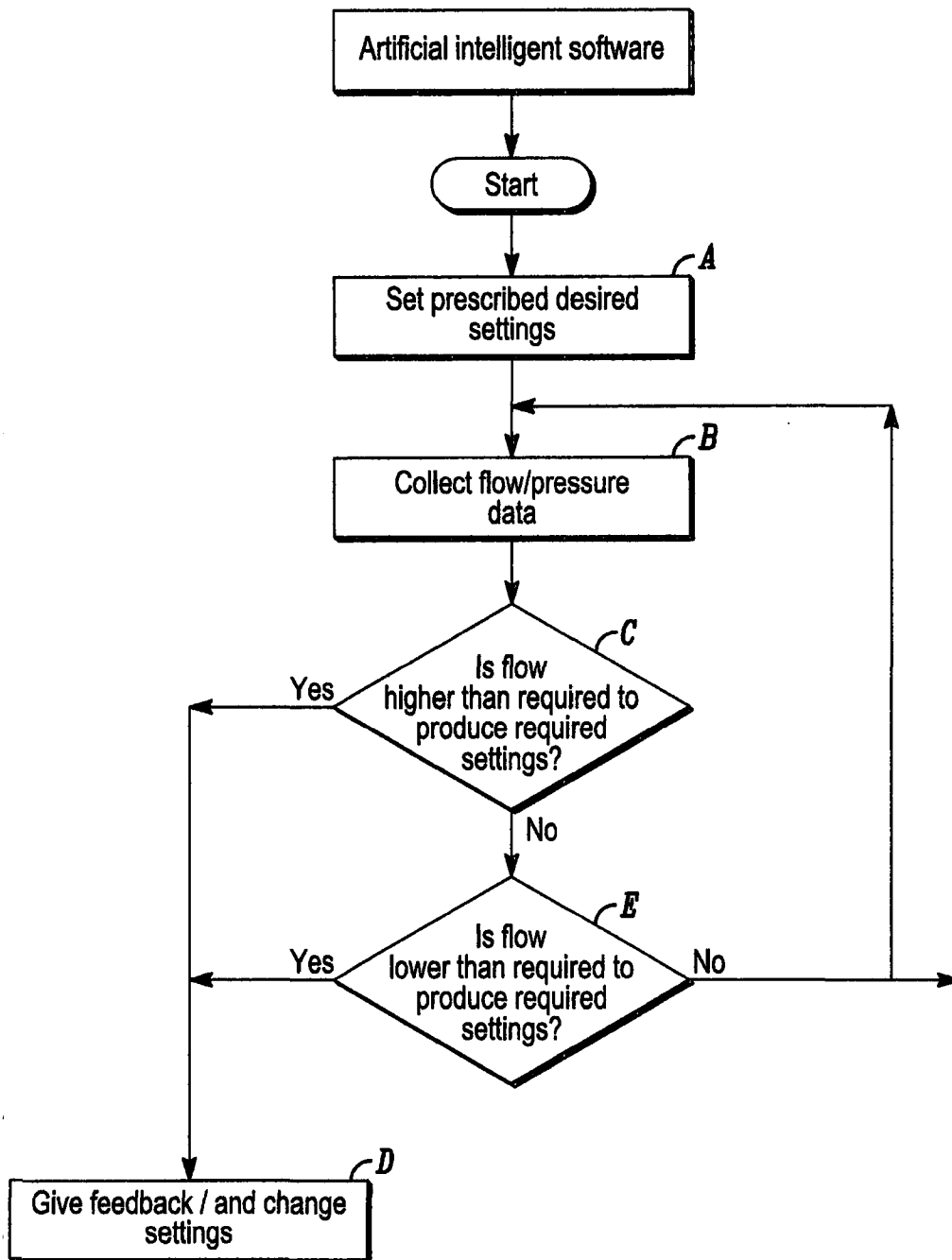


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/000456

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00 A61M16/20 A63B23/18
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61M A63B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 581 596 B1 (TRUITT PATRICK W [US] ET AL) 24 June 2003 (2003-06-24) abstract; figures 1,8, 13, 9, 11 column 4, lines 2-60 column 5, lines 1-9 column 12, lines 51-67 column 13, lines 1-17 page 13, lines 37-67 column 14, lines 1-40	1-10
X	EP 1 897 576 A1 (ACTEGY LIMITED [GB]) 12 March 2008 (2008-03-12) abstract; figures 2, 5, 14, 15, 16 paragraphs [0001], [0048], [0054], [0056]	1,2,4-10
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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
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- "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
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Date of the actual completion of the international search 20 January 2015	Date of mailing of the international search report 27/01/2015
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Moraru, Liviu

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/000456

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/127092 A1 (PELEROSSI RICHARD K [US] ET AL) 10 July 2003 (2003-07-10) the whole document	1-10
A	----- EP 1 103 287 A2 (DHD HEALTHCARE CORP [US] SMITHS MEDICAL ASD INC [US]) 30 May 2001 (2001-05-30) the whole document -----	1-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/GB2014/000456

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