March 21, 1967 H. GOLDFARB 3,310,050

MASSAGING GARMENT WITH VIBRATORS LOCATED IN BACK AND CHEST SECTIONS

Filed April 2, 1964

FIG. 1.

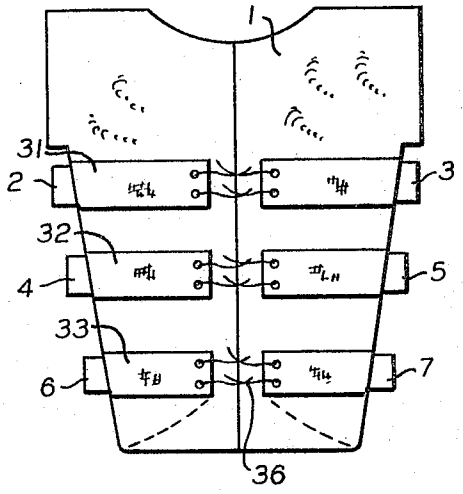


FIG. 2.

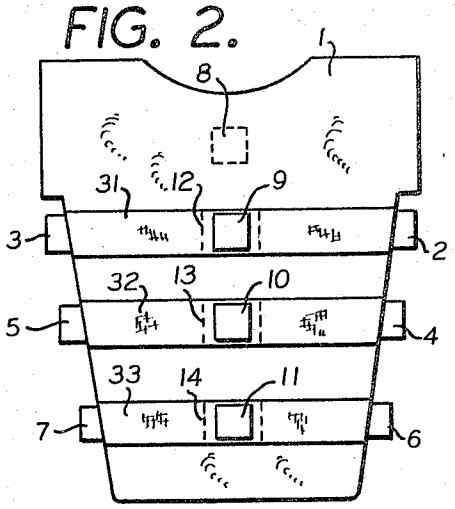


FIG. 3.

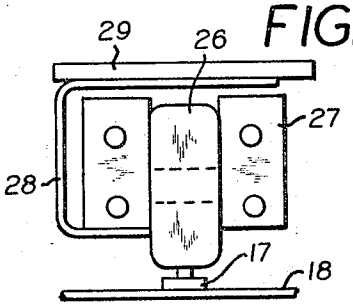


FIG. 4.

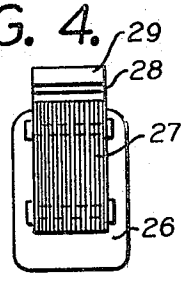


FIG. 6.

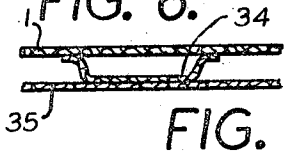


FIG. 5.

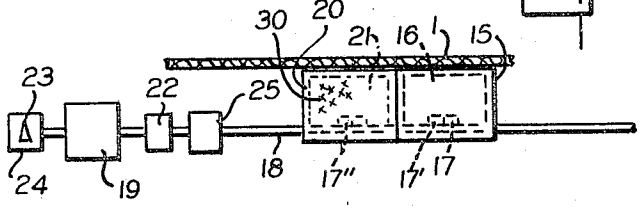
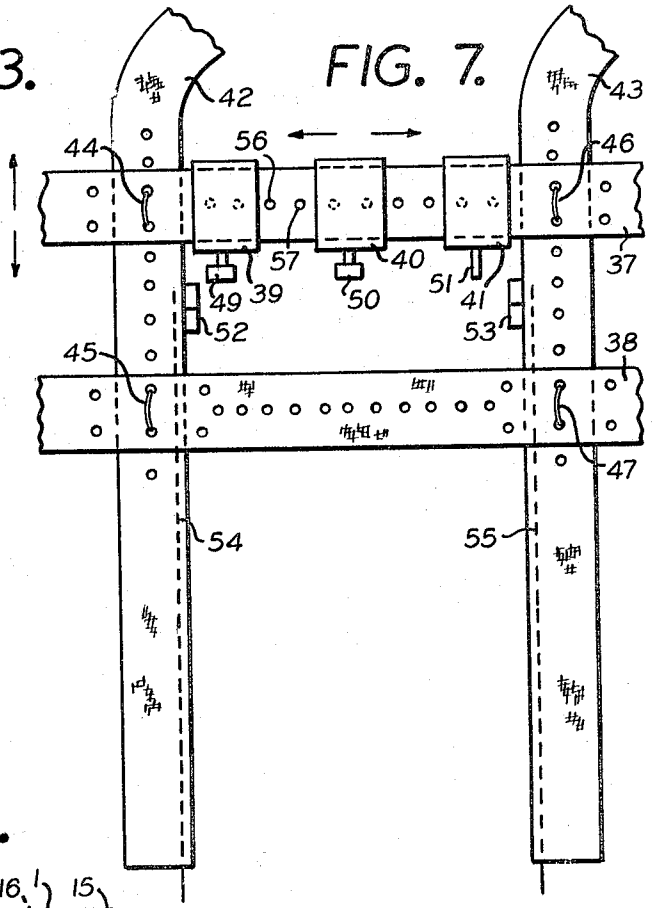


FIG. 7.



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3,310,050

MASSAGING GARMENT WITH VIBRATORS LOCATED IN BACK AND CHEST SECTIONS

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9 Claims. (Cl. 128—41)

This invention relates to the application of mechanical vibrations to the human body, especially external portions thereof, such as the chest.

One of the objects of the invention is to provide a number of vibrators, especially of the electro-mechanical type, to the chest and to support these vibrators on a vest-like structure or harness-type configuration in adjustable positions.

A more specific object of the invention is to provide a vest or harness adapted to carry a number of electro-mechanic vibrating means in adjustable positions so as to fit a great number of persons of different physiological structures in a manner readily operable, without much discomfort, and for home use.

A more specific object of the invention is to provide a supporting structure for a number of electro-mechanical vibrators of adjustable positions which, once fitted to the patient by his doctor, will apply predetermined mechanical pulsations to predetermined parts of his body, especially the pulmonary lobe with a view of relieving him with a minimum of discomfort from the accumulation of mucus in his bronchial tract.

Still another object of the invention is a device for percussing or vibrating the chest of a patient by means of an electro-mechanical vest or harness supporting a number of electro-mechanical vibrators in adjustable positions in which simultaneously with the mechanical support or positioning of a vibrator, an electrical connection of the vibrator to one or several sources of pulsating energy is established.

Still another object of the invention is a device to provide the patient with the means of self-administration of such treatments and also to provide therapists and operators with a less tiring means of administering postural treatment.

These and other objects of the invention will be more fully apparent from the drawings annexed hereto, in which

FIG. 1 represents in front view a device embodying certain principles of the invention;

FIG. 2 represents a corresponding rear view;

FIGS. 3 and 4 represent in front and side views, respectively, an electro-mechanical vibrating unit as applied for the realization of the invention in one form of its embodiment.

FIG. 5 shows part of the device of FIGS. 1 and 2, and more specifically a supporting pocket at a large scale and in greater detail;

FIG. 6 shows the wiring connections for the arrangement of FIG. 5.

FIG. 7 shows a modification of the embodiment illustrated in FIGS. 1 and 2.

As apparent from FIGS. 1 and 2, the device consists of a vest structure schematically indicated at 1, and made of natural or man-made textile material. Vest 1 should be designed to be fairly universal in fit having a front, back and side without sleeves. It is preferably made of soft material such as cotton flannel, so as not to be abrasive to the skin and yet be strong enough to support the electro-mechanical devices mounted thereon.

These devices may consist, as indicated schematically in FIGS. 1 and 2, at 2 to 11, of electro-mechanical vibrators of the type shown in greater detail in FIGS. 3 and 4, as will be described further below.

Vibrators 2–11 are held in vest 1 in pockets schematically indicated in FIG. 2 at 12, 13 and 14, distributed for example as shown in FIGS. 1 and 2 in three rows of three vibrators each, with an additional vibrator 8 being placed in an elevated position on the back between the scapular areas.

Vibrating units 2–11 are operated in parallel from a 110 volt A.C. 60 cycle main source as schematically indicated in FIGS. 5 and 6, where the specific pocket is shown at 15 with electro-mechanical vibrator 16 placed therein and connected by a disconnectable connection device consisting of a miniature plug and socket connection, schematically indicated at 17, 17', to a multi-wire cable schematically indicated at 18, and which in turn terminates in a more or less standard plug, schematically indicated at 19.

By this disconnecting connection device 17, 17' and removing vibrator 16 from pocket 15 and placing it into another pocket such as schematically indicated in FIG. 5 at 20, connection can be established of vibrator 16 in its new position through another connector part provided in pocket 20 and schematically indicated at 17'' which in turn is also connected to cable 18 and thereby to power source 19, so as to cause vibrator 15 in its new position 21 on vest 1 to be operative on a different portion of the body carrying vest 1.

In accordance with a further feature of the invention a cyclic timer switch of otherwise well known structure and remotely situated from the vest itself, as schematically shown in FIG. 5 at 22, will switch power sequentially from the lowest to the middle to the upper row of vibrators 2–8 respectively.

Any other type of switching may be provided in accordance with doctor's prescription and the specific conditions underlying a particular case.

In a preferred application of the invention power is maintained in each row of vibrators for about 30 seconds at a time.

Amplitude of vibration can be controlled by means of a rheostat schematically indicated at 23 on switch box 24 connected to power source 19.

Frequency of vibration will be controlled by the frequency of the power source in otherwise well known manner. Another means for controlling the frequency of vibration consists of arranging frequency dividers and multipliers in the circuit, as schematically indicated at 25 without departing from the scope of this invention.

A type of vibrator unit used in accordance with the invention is schematically indicated in FIGS. 3 and 4 in front and side elevations, respectively, in which the cable 18 is shown to supply over connection device 17, 17' coil 26 which energizes the laminated core 27 so as to operate magnetic armature 28 attached to one side of laminated core 27 in an elastic manner so as to be able to move up and down against the face of laminated core 27 in the rhythym of the current applied to coil 26. Armature 28 is provided with a plastic cover 29 to reduce its impact on the human body.

Since the vibrators tend to become warm when in continuous operation, the pocket portion of the vest is designed with a mesh backing schematically indicated in FIG. 5 at 30 to allow for air circulation.

A further attachment of the vibrators to the body is effected by a number of parallel belts of webbing, schematically indicated in FIGS. 1 and 2 at 31, 32 and 33 which are fitted over vest 1 and the pockets attached thereto, as schematically shown in FIG. 6 at 34 in the form of belting or webbing indicated at 35.

Ties or closures schematically indicated in FIG. 1 at 36 serve to fix the position of webbing belts 31, 32 and 33 either in front of the patient if pockets are used to vibrate or percuss the back of the patient or to fix the

position of belts 31, 32, 33 on the rear of the patient if pockets are used to vibrate or percuss the front of the patient.

Since the patient is to be maintained in a prone head-down position to facilitate removal of the mucus, the front closures are to be flat and nontraumatic.

As apparent from the example illustrated in FIGS. 1–7, each electro-mechanical vibrator unit is arranged in a position in which the vibrating element proper is caused to vibrate in a direction substantially perpendicular to extension of the skin of the human body to which it is attached, and the vibrations thus produced are communicated to the body at their appropriate positions by a coupling constituted by the material of the vest structure and especially by the additional attachment caused by the webbing belts described above.

It is of course possible without departing from the scope of the invention, to provide vibrating elements in other positions and also to provide other couplings from the vibrating element to the desired portions of the human body.

It is further possible, also without departing from the scope of the invention, to replace the electro-mechanical vibrators shown and described in the examples stated above, by other vibrating means, for example the electro-magnetic coil system operating an armature, by an electro-dynamic element operating a coil vibrating in an air gap and arranged to pulse directly or indirectly against the human body.

In a modification of the invention as illustrated in FIG. 5, the wiring 18 may be replaced by a bundle of airtubes, the pulsating energy source 19 by a motor-driven compressor and the timer 22 by a timer controlling valves opening and closing the different tubes contained in tube bundle 18 and which control small reciprocating piston devices replacing electro-mechanical vibrators 16, thereby dispensing with the necessity of feeding electrical current to vest 1.

In this way, the transducer elements may be operated as a closed hydraulic system in which a remote located motor-pump system repetitively pulses the hydraulic transducer elements (pistons) located on the vest.

A further modification will consist again of a closed hydraulic pneumatic system in which the actual transducer element rather than being a form of reciprocating piston driven shaft shall be a narrow lumen compartment within the vest fabric itself. This will expand and contract in balloon like fashion under the influence of the hydraulic or pneumatic fluid contained within it and pressurized by a remote located source.

Alternatively, the vibrating means can consist of a magnetostrictive element operated by an electro-magnetic coil system producing a field to vibrate said element.

Another source of mechanical vibrating is an electrical motor coupled to reciprocating means pushing against the human body directly or against coupling means surrounding or connected to the reciprocating units.

Such small motors with rotary motion converted to reciprocate motion, or small solenoids giving percussion as well as vibrating action are well known in the art and need not be described in detail.

It is desired, however, that the hammer portion of the vibrating unit is to be covered with a plastic plate, as schematically indicated in FIG. 3 at 29, which will either directly contact the body of the patient or will transmit vibration to the vest material. Examples of such motors are to be found in the field of electric toothbrushes or electric razors.

In an alternative embodiment of the invention described in FIG. 7, the vest structure includes the use of a harness-type arangement in which horizontal belts schematically indicated at 37, 38, and carrying vibrators 39, 40 and 41, are themselves held together by vertical belts 42, 43, respectively, and attached thereto at 44, 46 and 47, respectively, by means of prongs or buckles fitting into openings provided on vertical belts 42, 43 as well as horizontal belts 37, 38, respectively. This permits adjustment of the entire belt structure in horizontal spacings as well as vertical spacings and adaption to its various requirements of the body of the patient, as well as to the specific medical effects desired by the doctor.

Vertical belts 42, 43 are extended to both sides of the human body so as to permit displacement of horizontal belts 37, 38 from the front to the back and conversely or, if necessary, arangement of horizontal belts 37, 38 on the front as well as on the back of the patient, all supported on vertical straps 42, 43.

In addition, of course, any number of vertical and especially of horizontal straps may be provided without departing from the scope of the invention, and furthermore horizontal straps 37, 38 may be extended over the entire body in the manner indicated in FIGS. 1 and 2, and especially in FIG. 1, and provided with closure devices similar to those shown in FIG. 1 at 36, or any other appropriate closing means without departing from the scope of this disclosure.

As further apparent from FIG. 7, vibrators 39, 40, 41 may be held directly on belt 37, 38 attached in adjustable position on belt 37, 38.

Simultaneously, electrical connection may be effected by connecting a connecting device consisting of a miniature plug, schematically indicated in FIG. 7 at 49, 50 and 51, which can be connected to a multi socket connecting device provided on one or both of belts 42 and 43 as schematically indicated at 52, 53. Devices 52, 53 are of the type permitting a number of plugs of the type 49, 50, 51 attached to vibrators 39, 40, 41, respectively, to be connected to the common multiwire cable schematically indicated at 54, 55 leading to a common power supply or to a standard main plug not shown.

The harness type arrangement shown in FIG. 7, in which the vibrator belts themselves are held together by belts rather than in a fixed vest structure, may be likened to a parachute harness; this means that it permits the position of the vibrator on the belts to be varied by simply fixing the vibrator in a position on the belt. Such fixation may be effected for example by providing on the back of the vibrator press prongs, not shown, and fitting into corresponding press sockets schematically indicated in FIG. 7 on belt 37 at 56, 57.

The fixation may also be accomplished by a buckle attached to the back of the vibrators and slidable on the upper edges of horizontal belts 37, 38, or some other fastening means otherwise well known in the art, without departing from the scope of this disclosure.

In this manner it will be possible for the doctor to arrange the vibrators in positions determined by the chest anatomy of the patient and preferably in such a way that the vibrators will act on all lobes.

Percussion of the anterior chest may be accomplished by reversing the harness or vest, or by placing vibrating units on both the anterior and posterior aspects of the harness or vest.

Based on experience, the frequency range for said vibrating means has been found to be of the order of not more than 60 cycles per second, preferably of the order of not more than 1 to 5 cycles per second, and in some tests the power to be exerted by each of said vibrating means on the human body has been established as of the order of approximately 4 ounces.

While the invention has been described and illustrated by way of certain elements, connections of such elements, electrical and mechanical, and arrangements of such elements, the invention is not limited thereto, but may be applied in any appropriate form or manner whatsoever without departing from the scope of this disclosure.

What I claim is:

1. A therapeutic garment for applying predetermined mechanical pulsations to the pulmonary lobes of the body

to dislodge accumulations of mucus in the respiratory system,

said garment being dimensioned to overlie the chest and back of a body,

said garment carrying a plurality of means for impacting the body, means for securing said impacting means to said garment at locations adapted to directly and selectively overlie the chest and back, said impacting means adapted to impact the body at predetermined successive areas by applying pulsating forces thereto directed substantially perpendicular to the underlying skin with said forces having sufficient strength to dislodge accumulations of mucus in the underlying respiratory system.

2. A therapeutic garment in accordance with claim 1 wherein said means for impacting the body comprises a coil suprrounding a core and a flat armature reciprocal with respect to said core and against the skin,

said reciprocal armature extending substantially in a plane parallel to the skin and operative to reciprocate in a direction substantially perpendicular to said plane.

3. A therapeutic garment in accordance with claim 1 wherein said impacting means is activated by a source of electrical energy having a frequency in the order of not more than 1 to 5 cycles per second.

4. A therapeutic garment in accordance with claim 1 wherein the garment comprises a plurality of straps attached to each other,

said straps carrying means for attaching said impacting means at predetermined areas.

5. A therapeutic garment in accordance with claim 4 wherein said impacting means is capable of exerting a power in the order of approximately 4 ounces.

6. A therapeutic garment in accordance with claim 1 wherein said pulsating means comprises a plurality of sources of pulsating energy, said sources being interconnected by electrical connecting means attached to the structure of said garment.

7. A therapeutic garment in accordance with claim 6 wherein said electrical connecting means comprises a number of outlets and adjustment of said impacting means can be effected by displacing said impacting means from one outlet to another.

8. A therapeutic garment for applying predetermined mechanical pulsations to the pulmonary lobes of the body to dislodge accumulations of mucus in the respiratory system, said garment being dimensioned to overlie the chest and back of a body,

said garment carrying a plurality of impacting means for impacting the body, means for securing said impacting means to said garment at locations adapted to directly and selectively overlie the chest and back, said impacting means adapted to impact the body at predetermined successive areas by applying pulsating forces thereto directed substantially perpendicular to the underlying skin with said forces having sufficient strength to dislodge accumulations of mucus in the underlying respiratory system,

said garment comprising a plurality of vertical and horizontally extending straps with said horizontal straps carrying adjustment means for adjusting the location of said impacting means,

said impacting means being capable of exerting perpendicular forces on the skin of a human body in the order of approximately 4 ounces,

said impacting means comprising a ring-shaped electrical coil and an impact element for perpendicular reciprocation towards and away from the skin of the body.

9. A therapeutic garment in accordance with claim 8 and further including an electrical switch for selectively actuating selective ones of said plurality of impacting means with a predetermined pattern.

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RICHARD A. GAUDET, *Examiner.*

L. W. TRAPP, *Assistant Examiner.*

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(19) United States

(12) Patent Application Publication

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(43) Pub. Date: Apr. 7, 2016

Shockley, JR. et al.

(54) **SELF-CONTAINED PORTABLE POSITIONABLE OSCILLATING MOTOR ARRAY INCLUDING DISPOSABLE AND/OR RECYCLABLE PORTIONS**

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(72) Inventors: **Harold David Shockley, JR.**, Austin, TX (US); **Geoffrey Albert Marcek**, Austin, TX (US); **Robert Wiley Ellis**, Miramar, FL (US)

(21) Appl. No.: **14/876,504**

(22) Filed: **Oct. 6, 2015**

Related U.S. Application Data

(60) Provisional application No. 62/060,772, filed on Oct. 7, 2014, provisional application No. 62/101,131, filed on Jan. 8, 2015, provisional application No. 62/183,819, filed on Jun. 24, 2015.

Publication Classification

(51) **Int. Cl.**

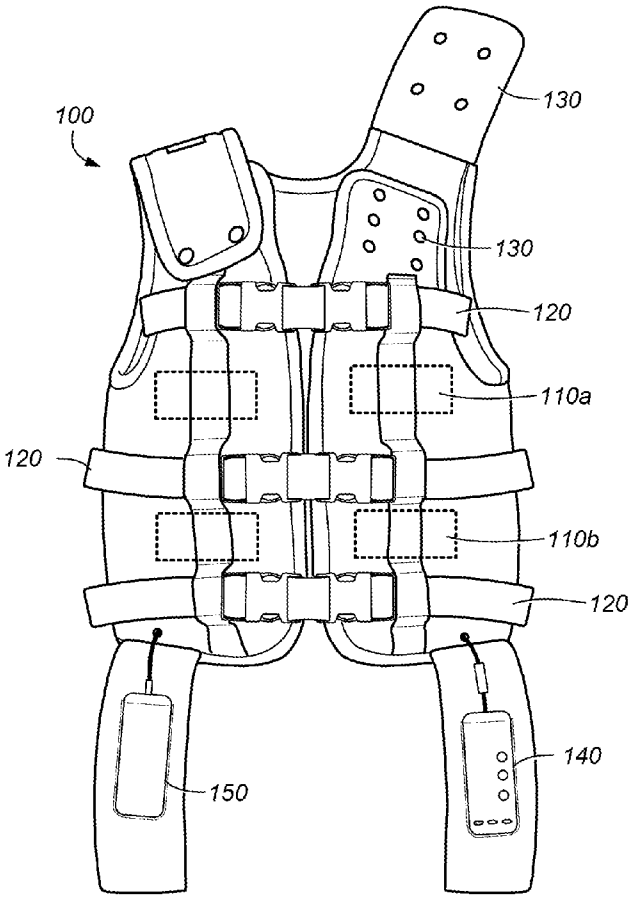
A61H 1/00	(2006.01)
A61H 23/02	(2006.01)

(52) **U.S. Cl.**

CPC ***A61H 1/008*** (2013.01); ***A61H 23/02*** (2013.01); *A61H 2201/1207* (2013.01); *A61H 2201/1652* (2013.01); *A61H 2201/1678* (2013.01); *A61H 2201/50* (2013.01); *A61H 2201/0111* (2013.01)

(57) **ABSTRACT**

In some embodiments, a system and/or method may include an inner wearable harness worn, during use, on a torso of a subject which includes a flexible vest. The system may include a plurality of engines, each of which are contained in a flexible container, which when activated apply an oscillation force. The system may include a positioning system which allows positioning the flexible container such that the oscillation force is applied to at least one treatment area of the subject. The oscillation force may mobilize, during use, at least some secretions in an airway within the subject substantially adjacent the treatment area. The system may include an outer harness worn, during use, on a torso of a subject. The outer wearable harness, when activated, adjusts the oscillation force applied by at least some of the activated plurality of engines to the treatment area by providing a compressive force.



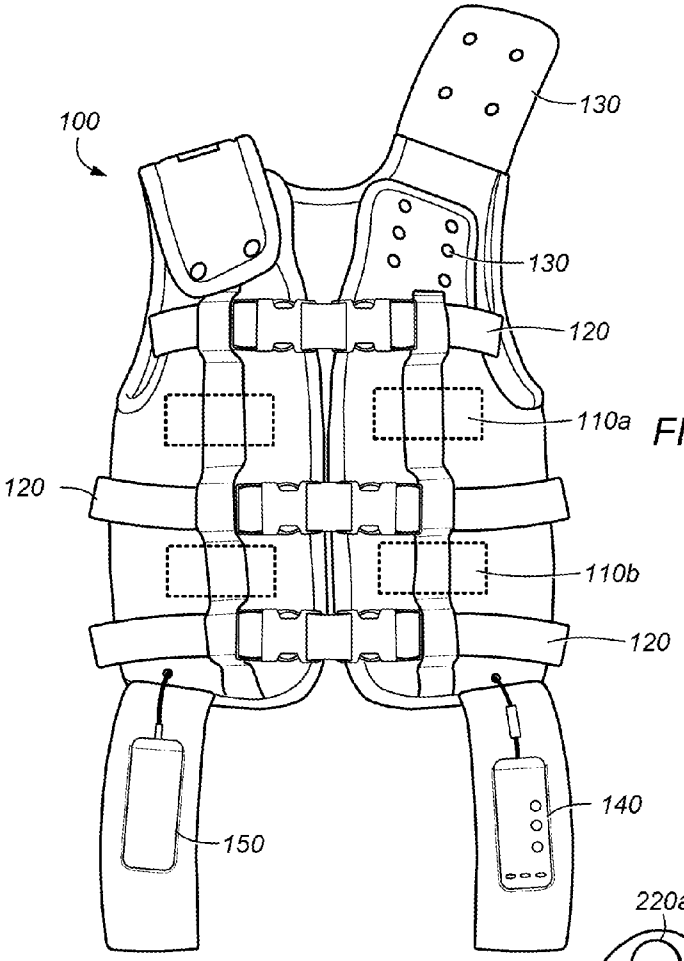

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FIG. 1

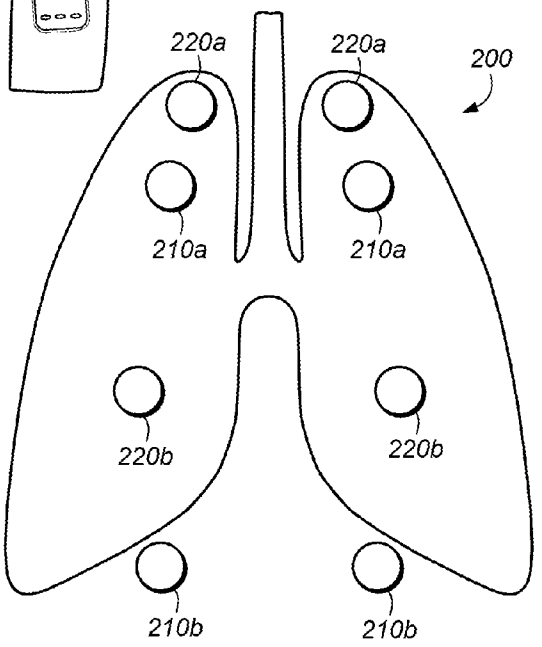
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FIG. 2

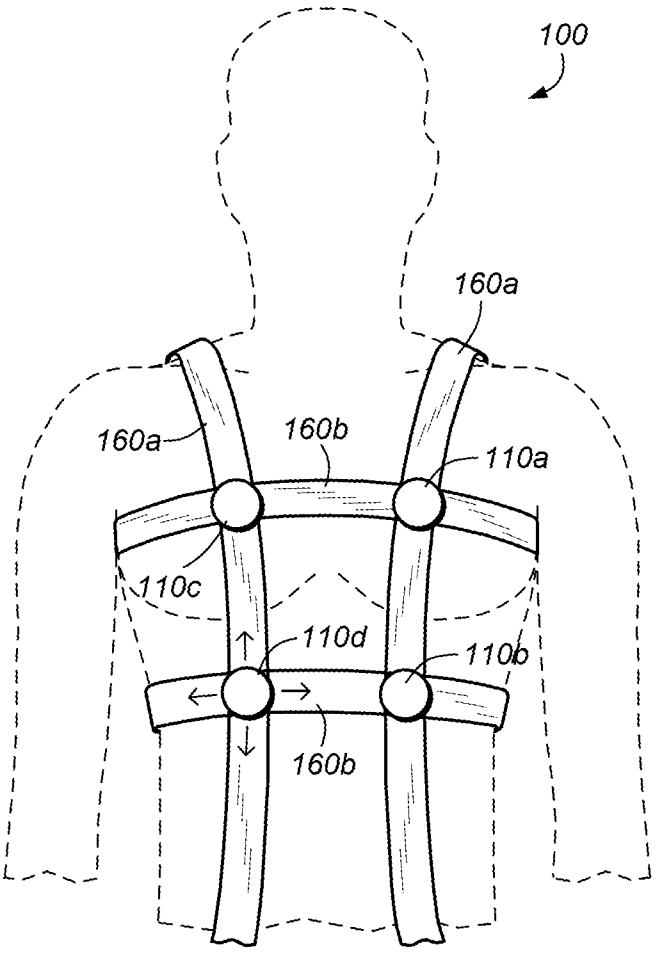

FIG. 3

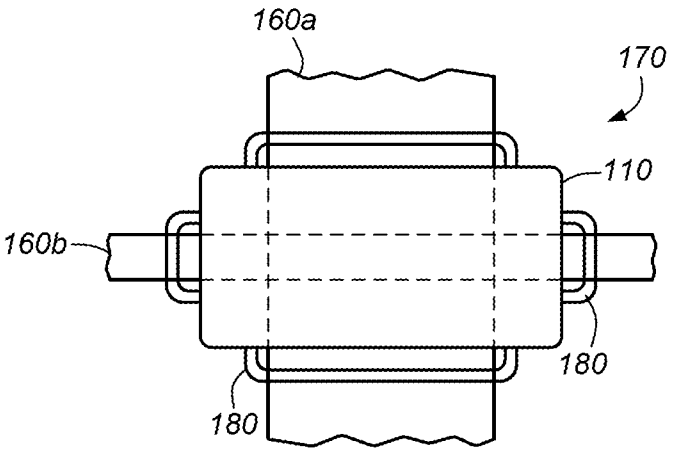

FIG. 4A

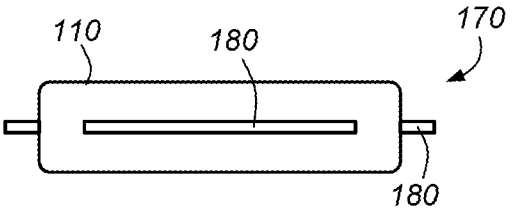

FIG. 4B

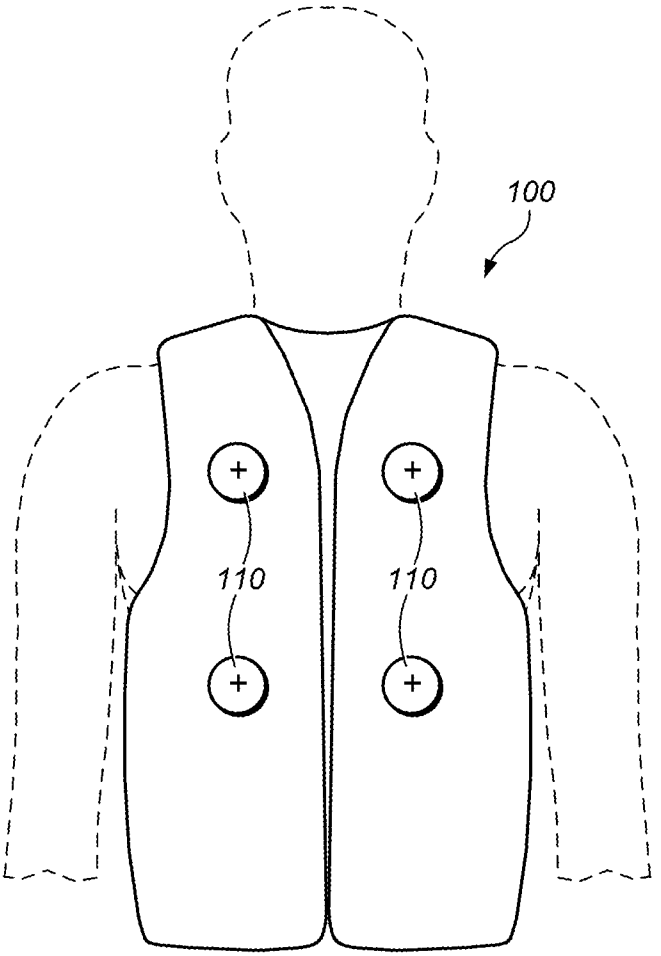

FIG. 5

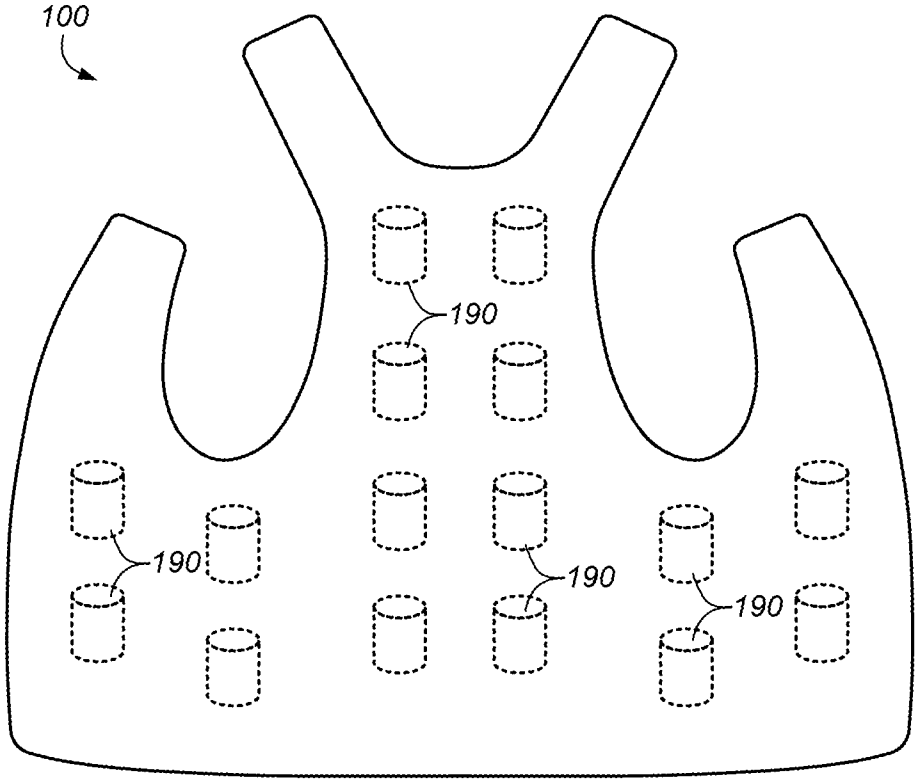

FIG. 6

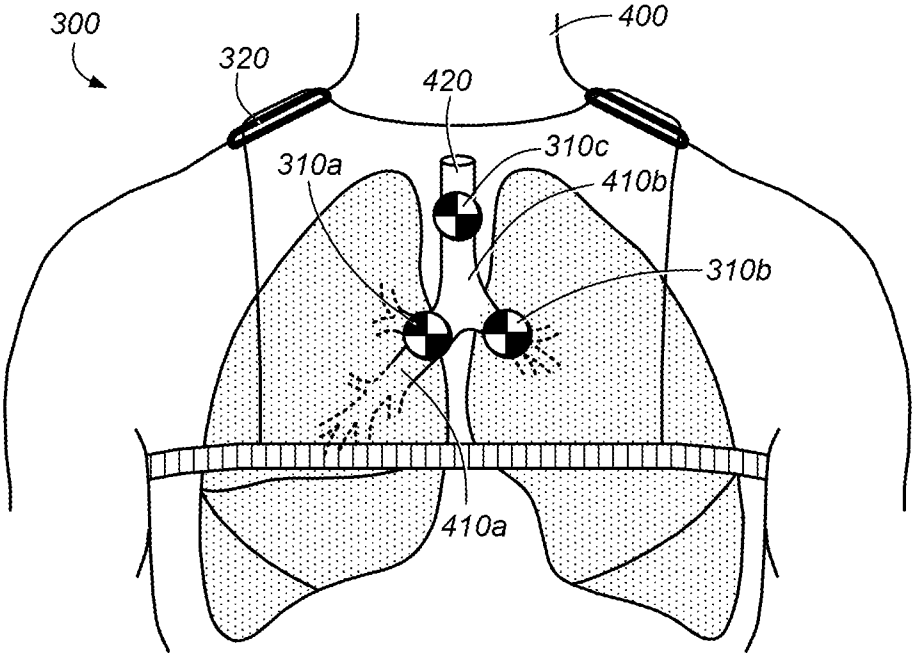

FIG. 7

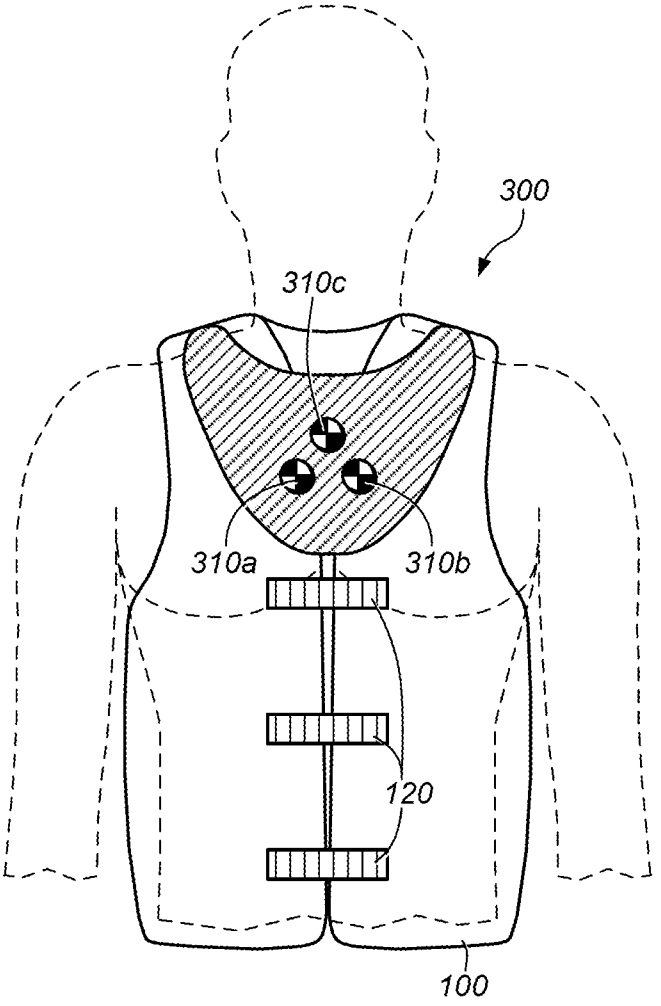

FIG. 8

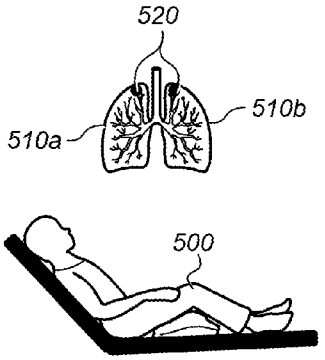

FIG. 9A

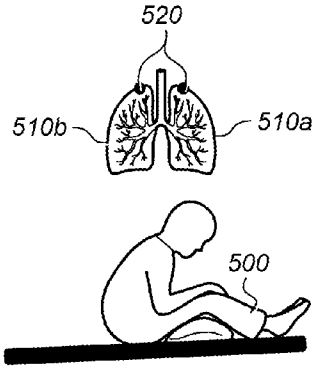

FIG. 9B

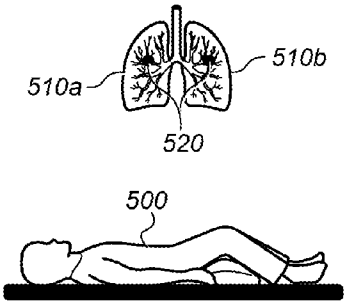

FIG. 9C

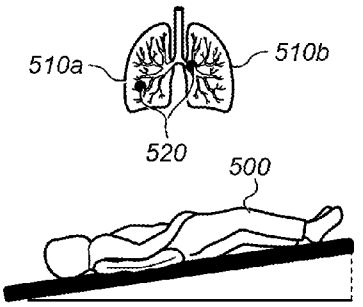

FIG. 9D

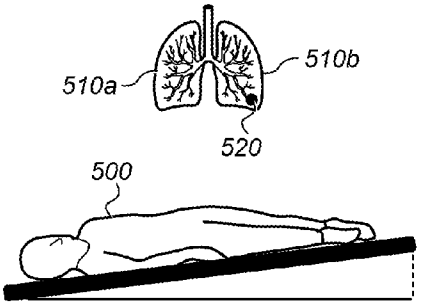

FIG. 9E

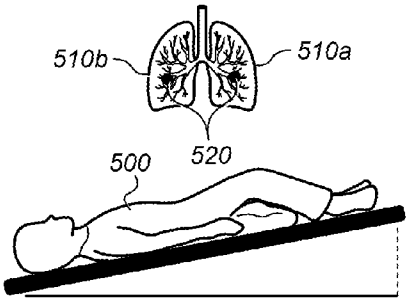

FIG. 9F

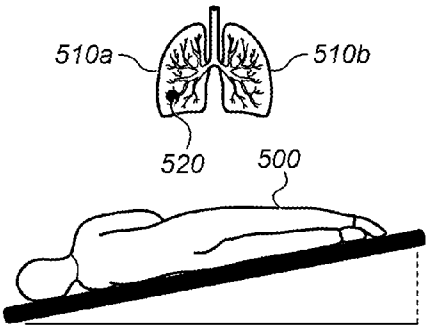

FIG. 9G

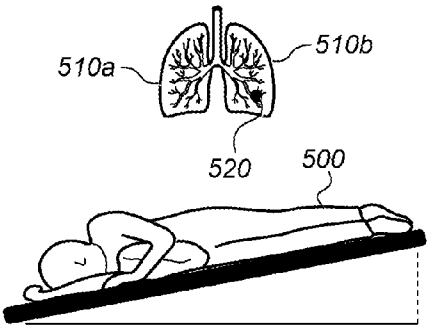

FIG. 9H

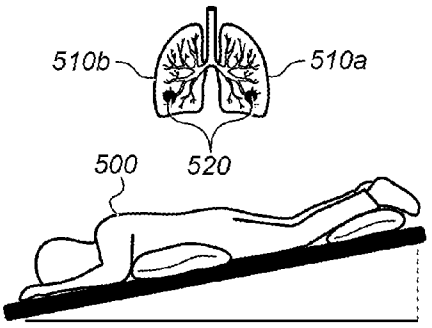

FIG. 9I

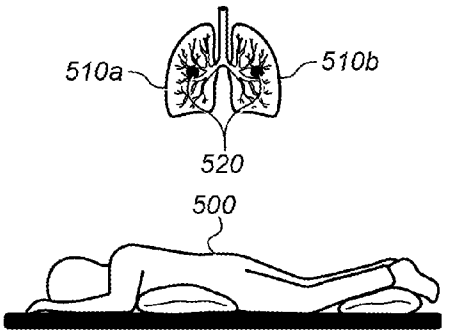

FIG. 9J

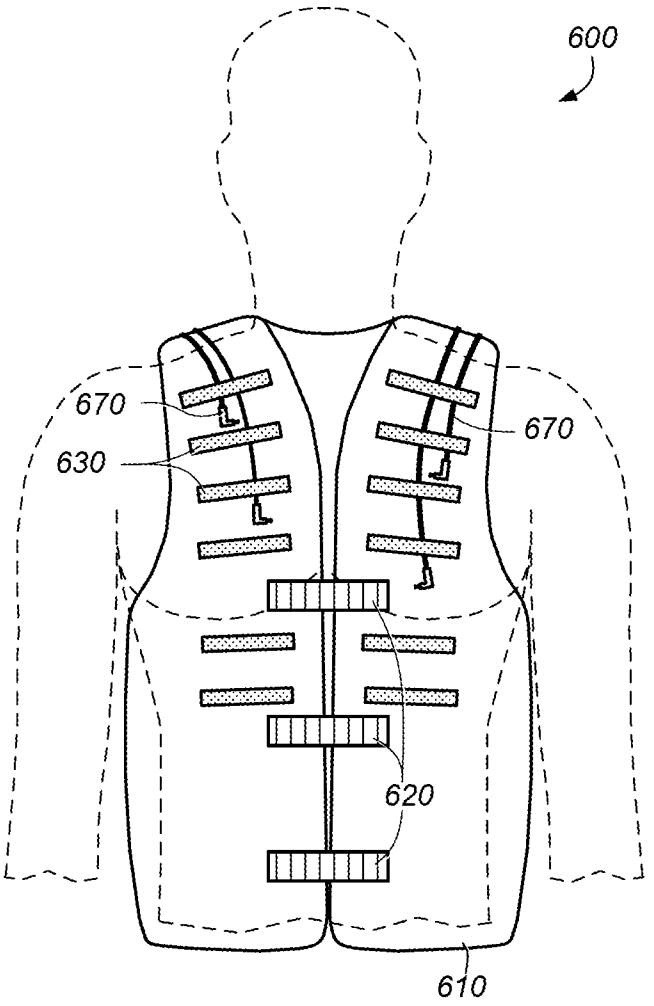

FIG. 10

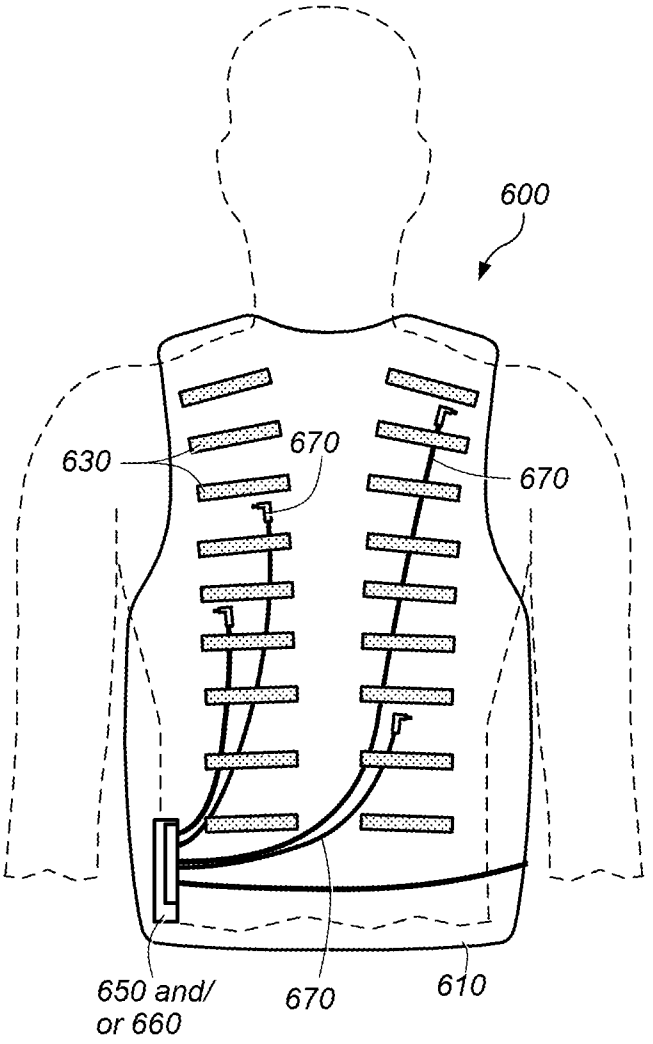

FIG. 11

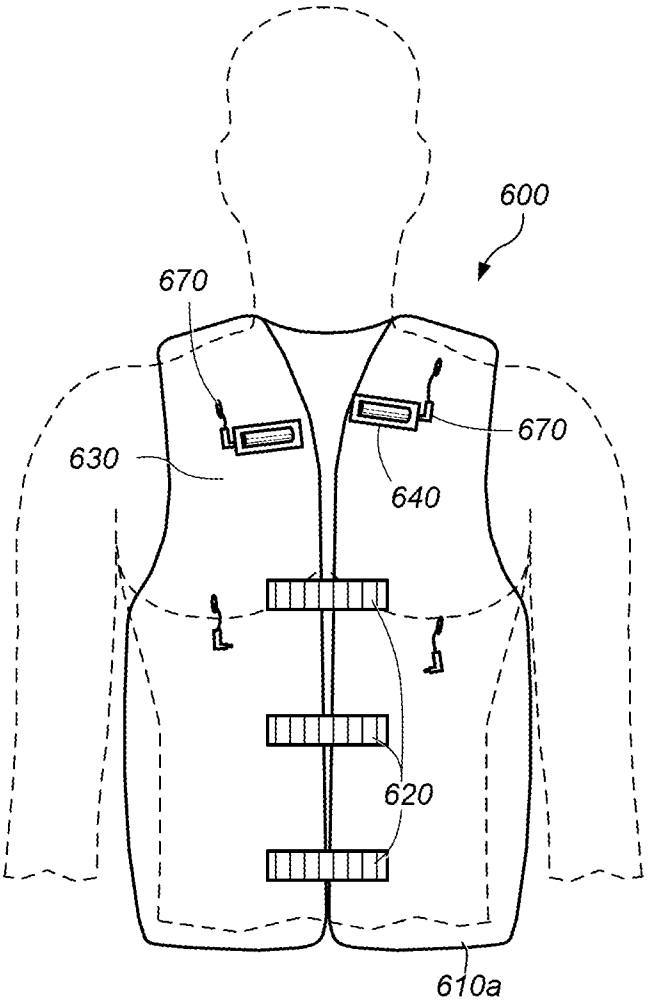

FIG. 12

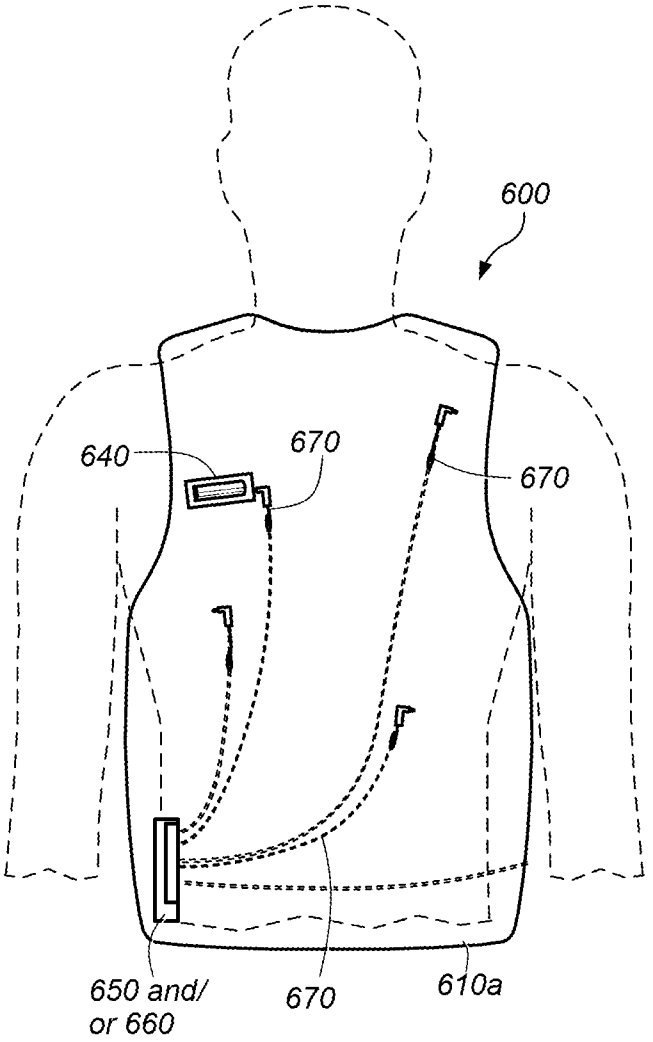

FIG. 13

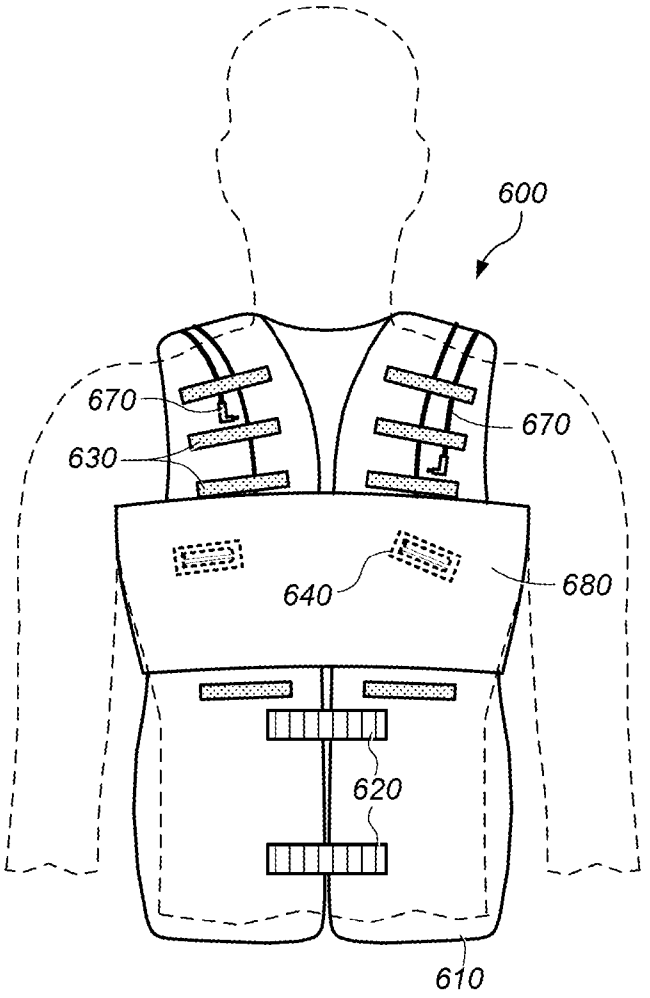

FIG. 14

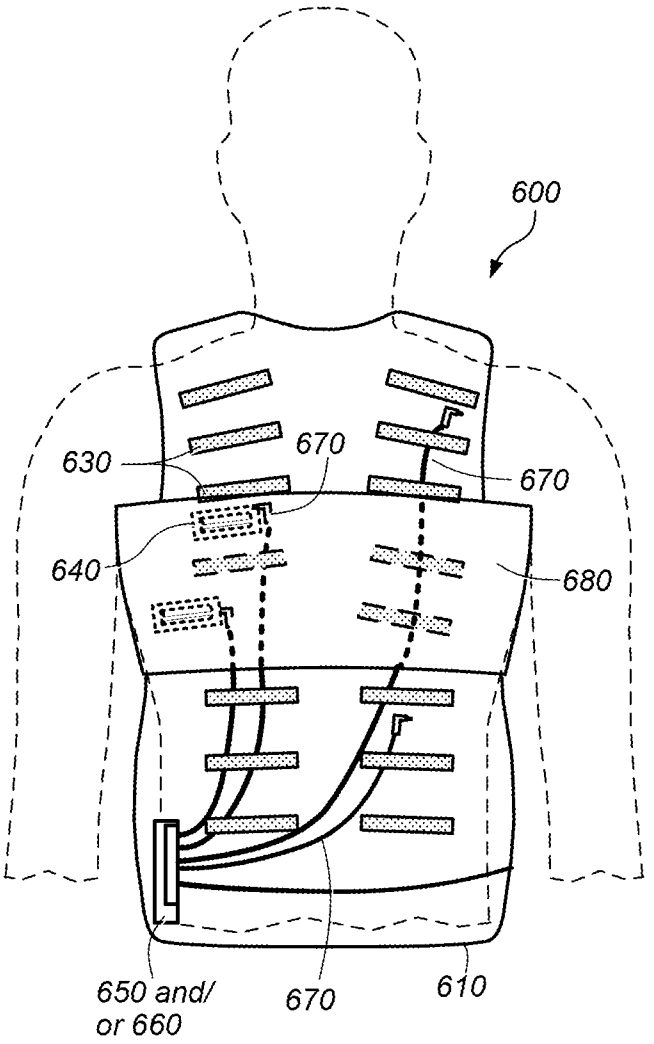

FIG. 15

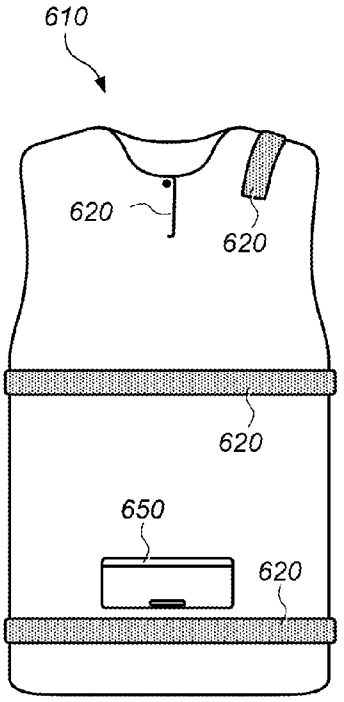
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FIG. 16

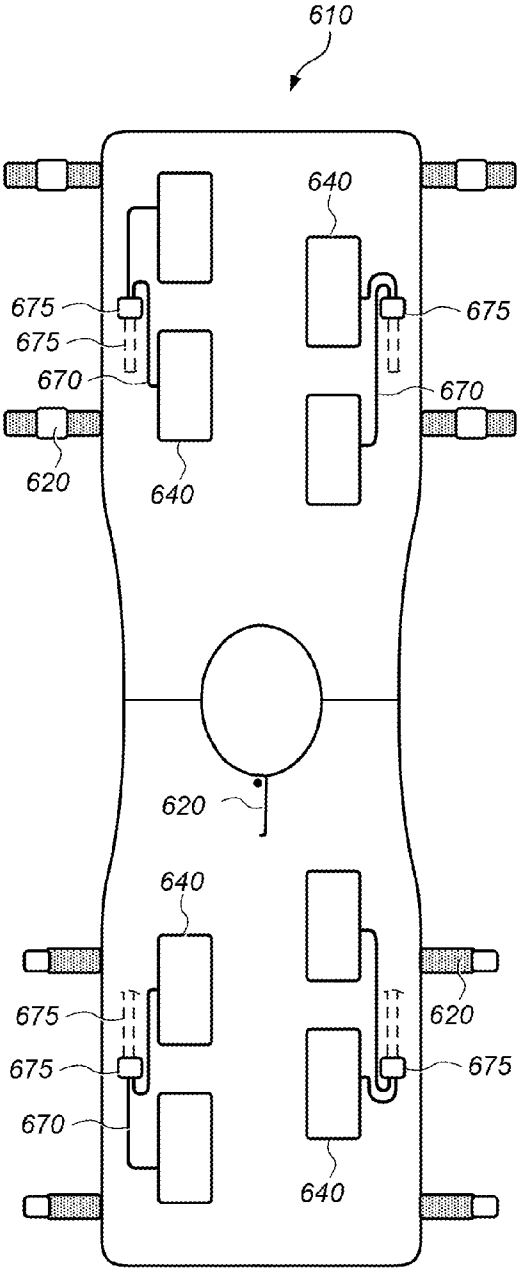
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FIG. 17

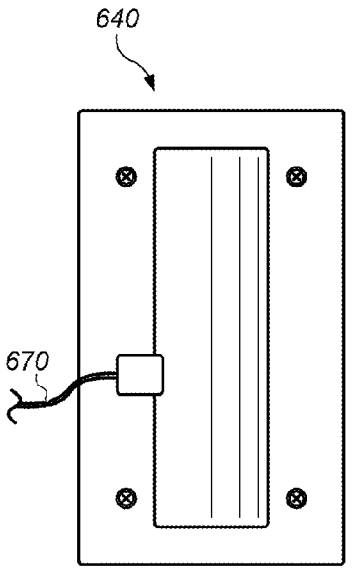


FIG. 18A

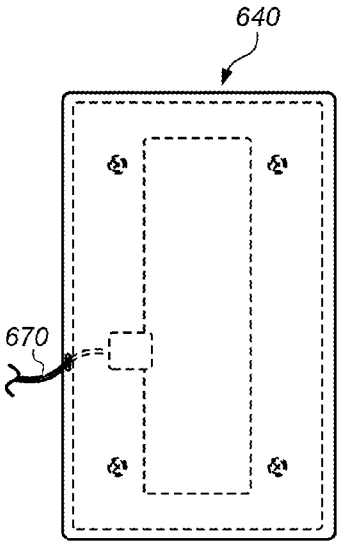


FIG. 18B

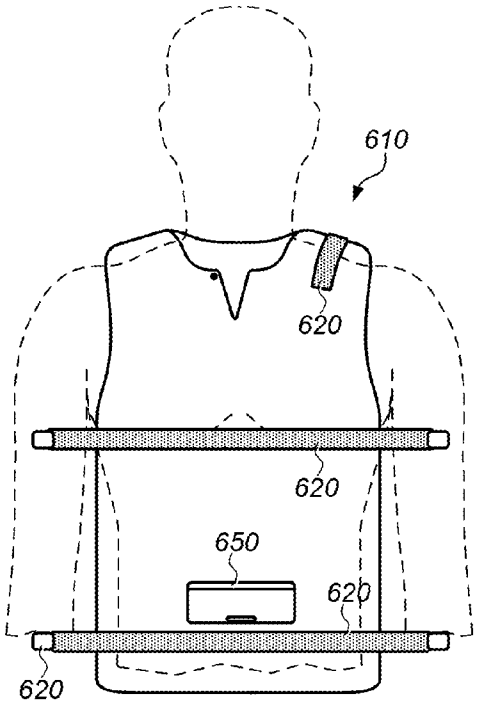


FIG. 19

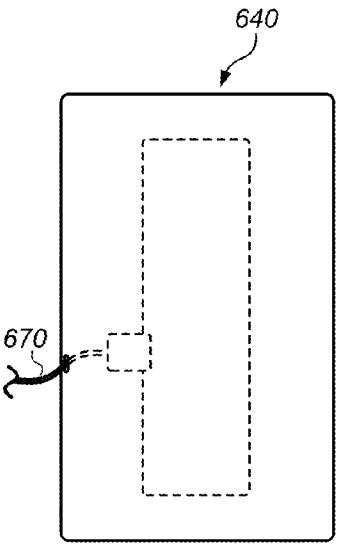
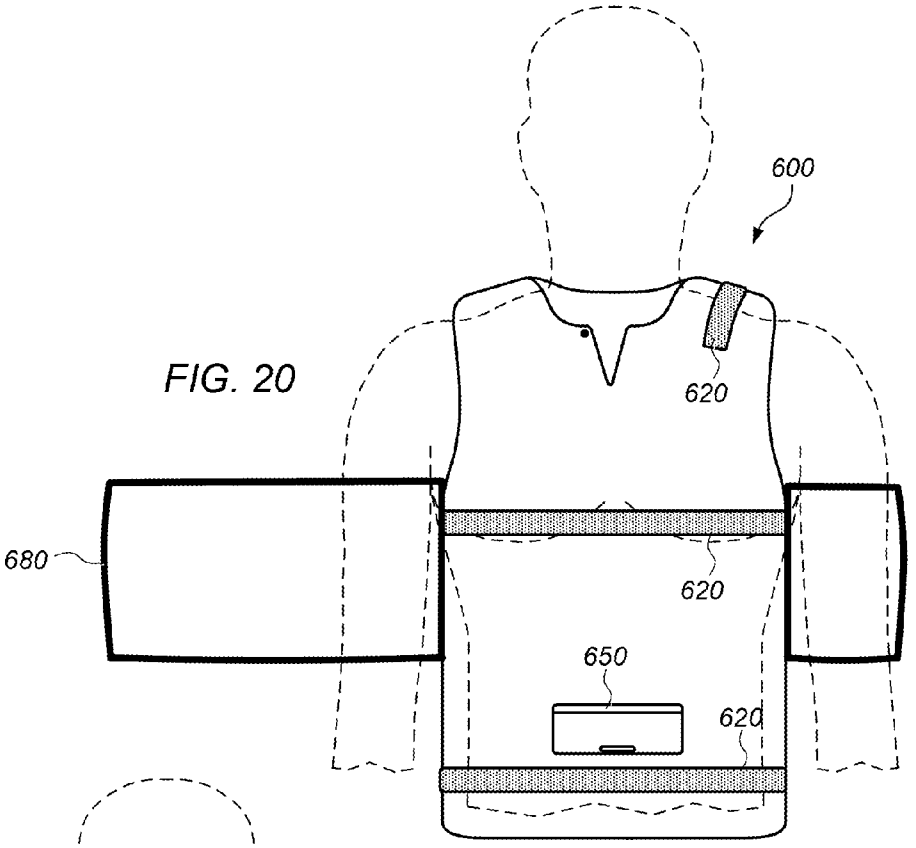


FIG. 18C

FIG. 20



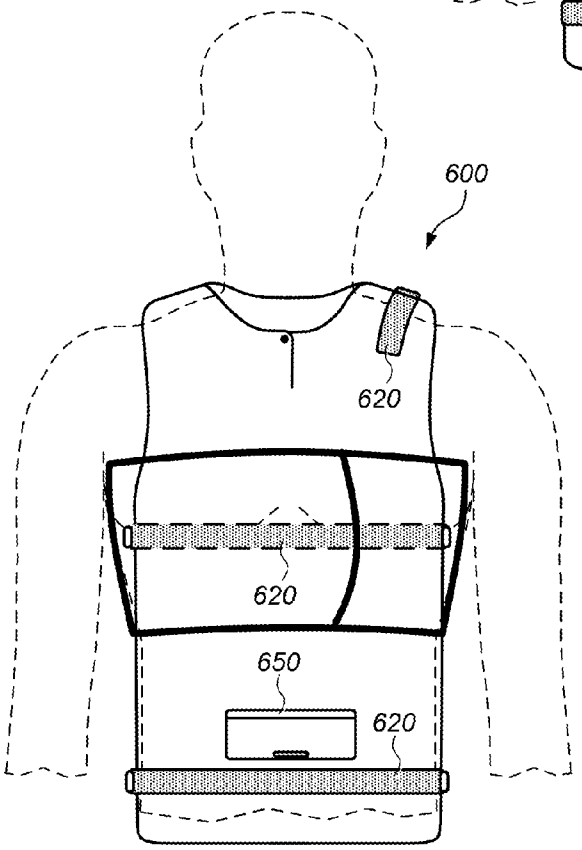
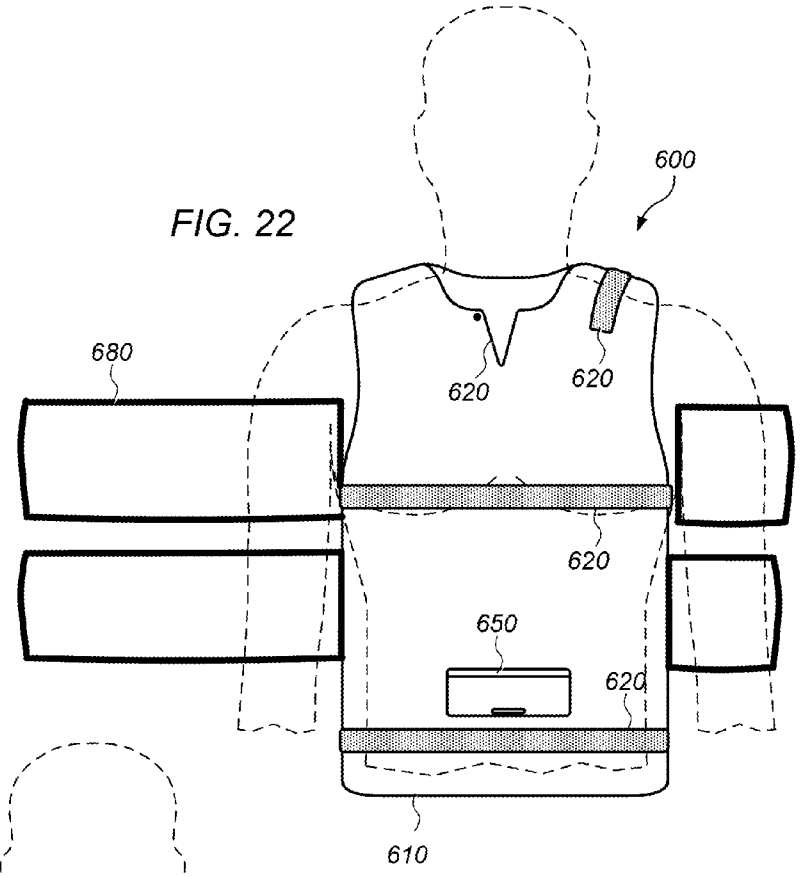


FIG. 21

FIG. 22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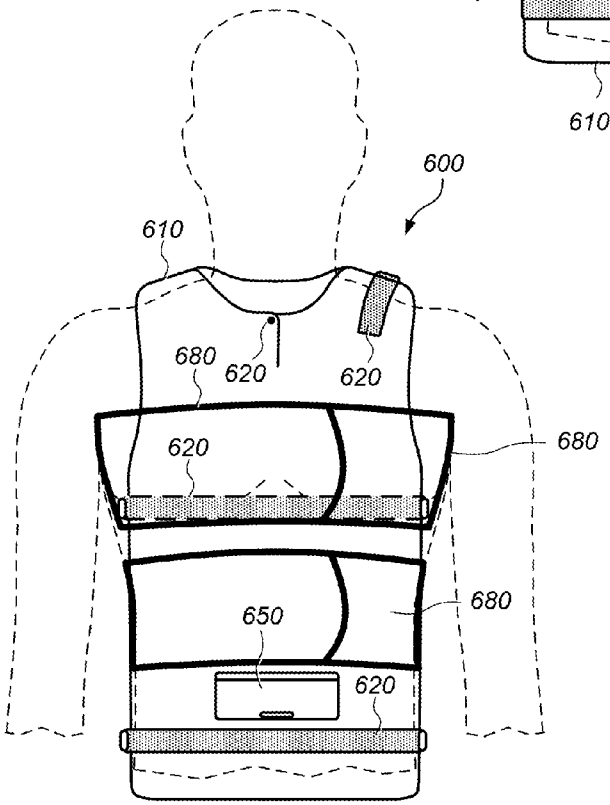
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FIG. 23

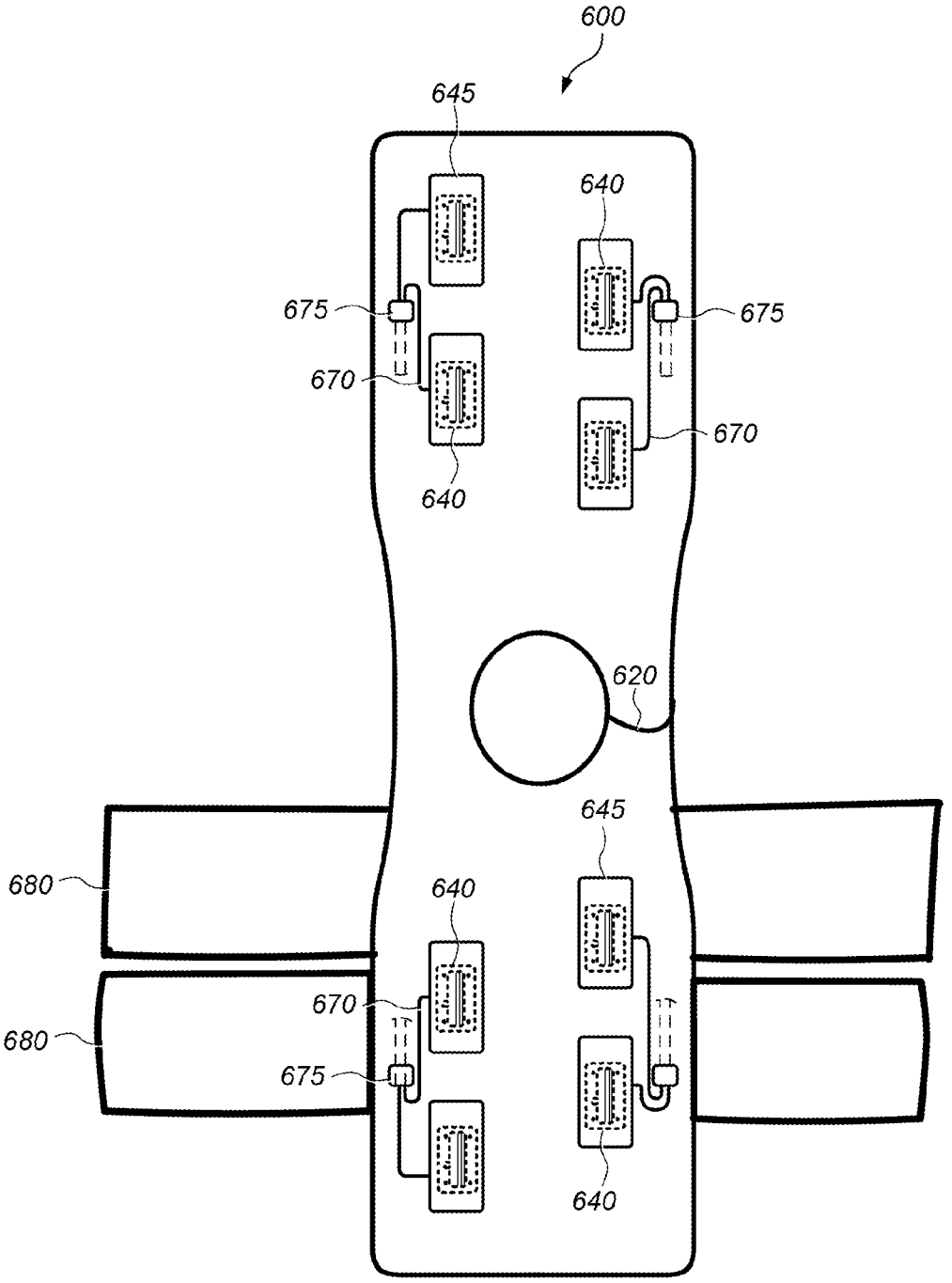

FIG. 24

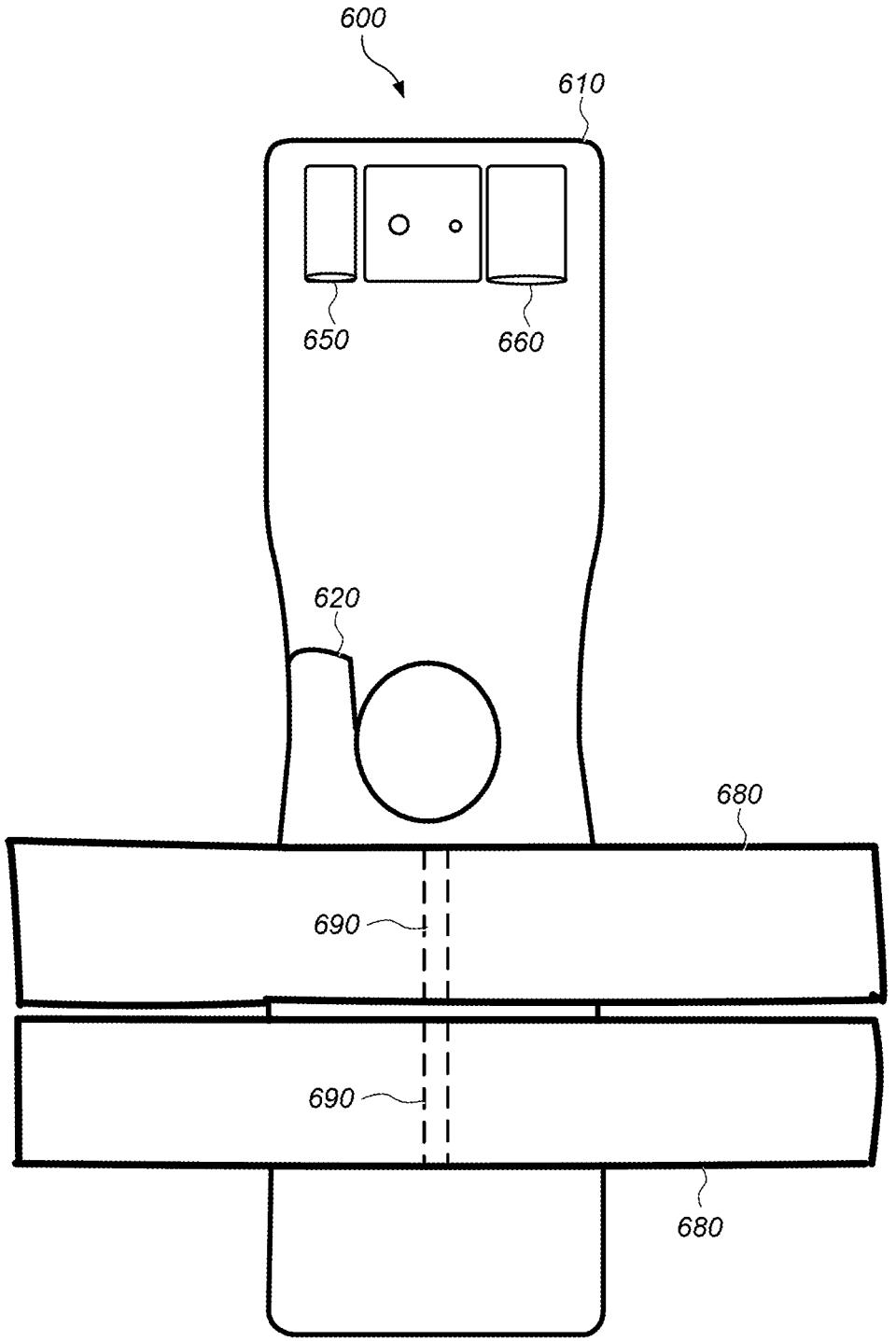

FIG. 25

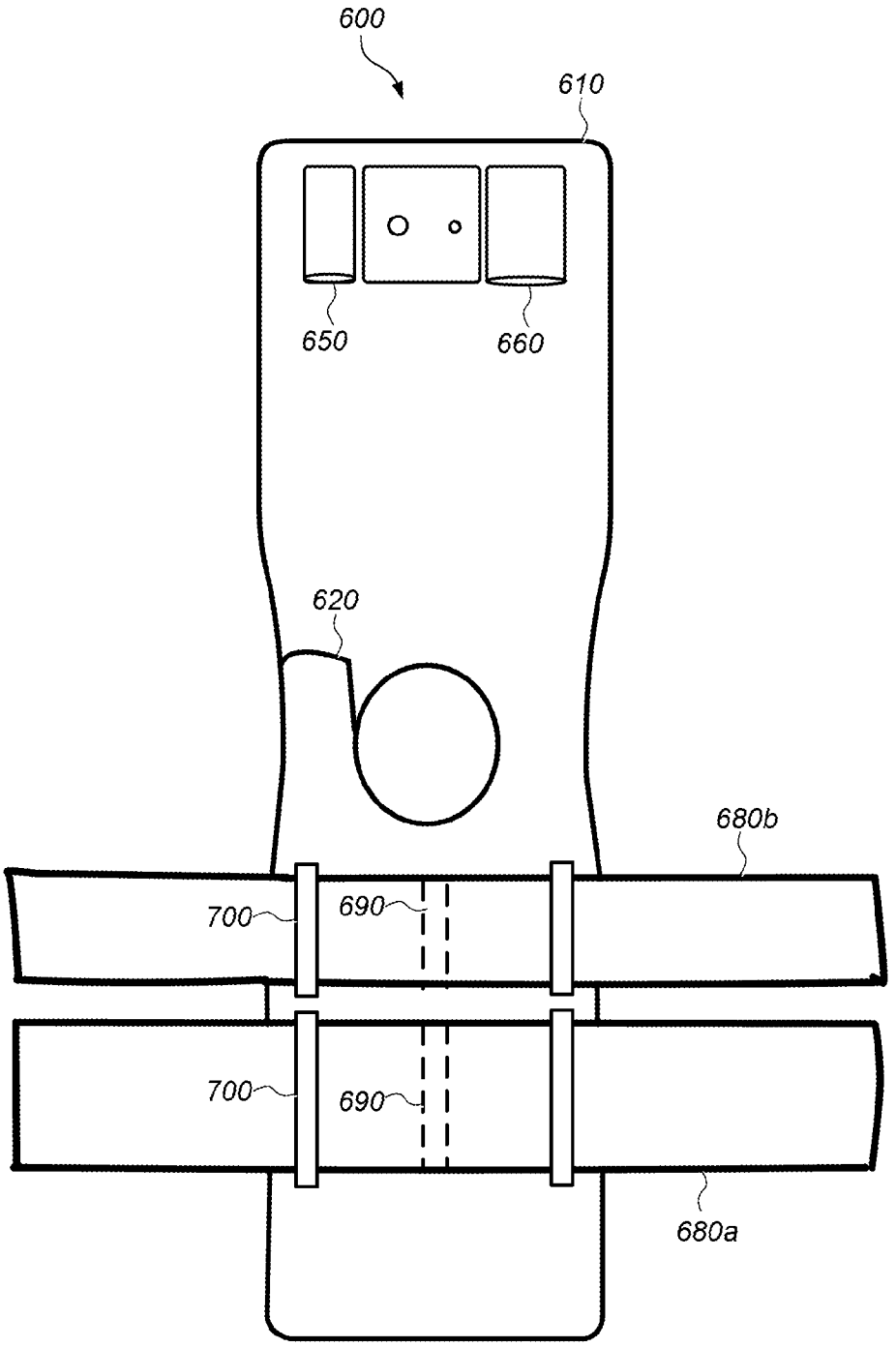

FIG. 26

SELF-CONTAINED PORTABLE POSITIONABLE OSCILLATING MOTOR ARRAY INCLUDING DISPOSABLE AND/OR RECYCLABLE PORTIONS

PRIORITY CLAIM

[0001] This application is a claims priority to U.S. Provisional Patent Application No. 62/060,772 entitled "CHEST WALL OSCILLATION VEST" filed on Oct. 7, 2014, U.S. Provisional Patent Application No. 62/101,131 entitled "SELF-CONTAINED PORTABLE HIGH FREQUENCY PHYSIOLOGICAL OSCILLATOR" filed on Jan. 8, 2015, and U.S. Provisional Patent Application No. 62/183,819 entitled "SELF-CONTAINED PORTABLE POSITIONABLE OSCILLATING MOTOR ARRAY" filed on Jun. 24, 2015, all of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present disclosure generally relates to respiratory therapies. More particularly, the disclosure generally relates to a method and system for high frequency upper chest wall oscillation therapy.

[0004] 2. Description of the Relevant Art

[0005] Subjects who are unable to mobilize their own lung secretions without assistance (subjects with, for example, chronic obstructive pulmonary disease (COPD)) are exceedingly common, which together account for over 1 million hospitalizations each year in the United States alone. Beta agonists, anti-cholinergics, and corticosteroids delivered in aerosolized forms are recommended in the treatment of COPD. These medications rely on deposition into distal airspaces to suppress airway inflammation or promote bronchodilation. Excessive mucous production and impaired airway mucociliary clearance can lead to airway plugging, and thereby reduce the deposition of and response to aerosolized medications. These considerations highlight the need for therapies that clear airways of mucus in the acute management of diseases such as cystic fibrosis, bronchiectasis (and other severe form of COPD), and certain neuromuscular diseases.

[0006] Manual percussion techniques of chest physiotherapy have been used for a variety of diseases, such as cystic fibrosis, emphysema, and chronic bronchitis, to remove excess mucus that collects in the lungs. To bypass dependency on a caregiver to provide this therapy, chest compression and oscillation devices have been developed to produce High Frequency Chest Wall Oscillation (HFCWO), a very successful method of airway clearance. High frequency chest wall oscillation (HFCWO) creates high velocity, low amplitude oscillation energy when applied through a vest worn over the thorax, and is used for airway mucus clearance in patients with cystic fibrosis, bronchiectasis, and neuromuscular disorders. Studies in patients with cystic fibrosis suggest that HFCWO applied via a vest is as effective as other modes of airway mucus clearance, including hand-held devices (e.g., flutter devices) and conventional chest physiotherapy. HFCWO offers the advantage that it can be performed in acutely ill patients who may be unable to use hand-held devices effectively, such as early in the course of hospitalization. Moreover, HFCWO can be performed without the assistance from trained health care personnel, and may therefore offer a practical advantage compared to chest physiotherapy.

[0007] Professional healthcare environments are required to constantly be vigilant regarding sanitation and cross contamination between patients. To this end medical equipment must be sanitized before being used again. However, sanitizing equipment is typically time consuming and/or expensive. As such much of the equipment used in healthcare environments which comes into direct contact with subjects is disposable (or covered by disposable sheaths). It is typically much easier and/or less expensive to throw away equipment which comes into contact with subjects as opposed to cleaning the equipment.

[0008] As such, it may advantageous to form a wearable HFCWO system with one or more disposable portions.

SUMMARY

[0009] In some embodiments, a system and/or method may include an inner wearable harness worn, during use, on a torso of a subject. The system may include a plurality of engines which when activated apply an oscillation force to at least one treatment area of the subject. At least some of the plurality of engines may be releasably couplable to the inner wearable harness. The system may include a positioning system which allows positioning at least one of the plurality of engines such that the oscillation force is applied to at least one of the treatment areas of the subject. The oscillation force may mobilize, during use, at least some secretions in an airway within the subject substantially adjacent the treatment area. The system may include an outer harness worn, during use, on a torso of a subject. The outer wearable harness, when activated, adjusts the oscillation force applied by at least some of the activated plurality of engines to the treatment area.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Advantages of the present invention may become apparent to those skilled in the art with the benefit of the following detailed description of the preferred embodiments and upon reference to the accompanying drawings.

[0011] FIG. **1** depicts a front perspective view of a representation of an embodiment of a portable high frequency chest wall oscillator system.

[0012] FIG. **2** depicts a front view of a representation of an embodiment of a pair of human lungs.

[0013] FIG. **3** depicts a front perspective view of a representation of an embodiment of a portable high frequency chest wall oscillator harness.

[0014] FIG. **4**A depicts a front view of a representation of an embodiment of an engine coupling system.

[0015] FIG. **4**B depicts a side view of a representation of an embodiment of an engine coupling system.

[0016] FIG. **5** depicts a front perspective view of a representation of an embodiment of a portable high frequency chest wall oscillator harness using a hook and loop coupling system positioned on a subject.

[0017] FIG. **6** depicts a front perspective view of a representation of an embodiment of a portable high frequency chest wall oscillator harness using sealable containers coupling system positioned on a subject.

[0018] FIG. **7** depicts a representation of an embodiment of a portable high frequency physiological oscillator harness positioned around a subject's neck.

[0019] FIG. **8** depicts a representation of an embodiment of a portable high frequency physiological oscillator harness

positioned around a subject's neck in combination with portable high frequency chest wall oscillator vest.

[0020] FIGS. **9**A-J depict representations of different areas of a subject's lungs which may require treatment using herein described systems and methods.

[0021] FIG. **10** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness positioned on a subject.

[0022] FIG. **11** depicts a rear view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness positioned on a subject.

[0023] FIG. **12** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness positioned on a subject.

[0024] FIG. **13** depicts a rear view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness positioned on a subject.

[0025] FIG. **14** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness and an outer harness positioned on a subject.

[0026] FIG. **15** depicts a rear view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness and an outer harness positioned on a subject.

[0027] FIG. **16** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness.

[0028] FIG. **17** depicts an interior view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness laid out in an open flat presentation.

[0029] FIGS. **18**A-B depict a first and a second opposing side view of a representation of a first embodiment of an engine.

[0030] FIG. **18**C depicts a side view of a representation of a second embodiment of an engine.

[0031] FIG. **19** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including unsecured fasteners positioned on a subject.

[0032] FIG. **20** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including secured fasteners as well as an inactivated outer harness positioned on a subject.

[0033] FIG. **21** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including secured fasteners as well as a single activated outer harness positioned on a subject.

[0034] FIG. **22** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including secured fasteners as well as two inactivated outer harnesses positioned on a subject.

[0035] FIG. **23** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including secured fasteners as well as two activated outer harnesses positioned on a subject.

[0036] FIG. **24** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including secured fasteners as well as two inactivated outer harnesses positioned on a subject.

[0037] FIG. **25** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including secured fasteners as well as two activated outer harnesses positioned on a subject.

[0038] FIG. **26** depicts a front view of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including secured fasteners as well as two activated outer harnesses positioned on a subject.

[0039] While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and may herein be described in detail. The drawings may not be to scale. It should be understood, however, that the drawings and detailed description thereto are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

[0040] The headings used herein are for organizational purposes only and are not meant to be used to limit the scope of the description. As used throughout this application, the word "may" is used in a permissive sense (i.e., meaning having the potential to), rather than the mandatory sense (i.e., meaning must). The words "include," "including," and "includes" indicate open-ended relationships and therefore mean including, but not limited to. Similarly, the words "have," "having," and "has" also indicated open-ended relationships, and thus mean having, but not limited to. The terms "first," "second," "third," and so forth as used herein are used as labels for nouns that they precede, and do not imply any type of ordering (e.g., spatial, temporal, logical, etc.) unless such an ordering is otherwise explicitly indicated. For example, a "third die electrically connected to the module substrate" does not preclude scenarios in which a "fourth die electrically connected to the module substrate" is connected prior to the third die, unless otherwise specified. Similarly, a "second" feature does not require that a "first" feature be implemented prior to the "second" feature, unless otherwise specified.

[0041] Various components may be described as "configured to" perform a task or tasks. In such contexts, "configured to" is a broad recitation generally meaning "having structure that" performs the task or tasks during operation. As such, the component can be configured to perform the task even when the component is not currently performing that task (e.g., a set of electrical conductors may be configured to electrically connect a module to another module, even when the two modules are not connected). In some contexts, "configured to" may be a broad recitation of structure generally meaning "having circuitry that" performs the task or tasks during operation. As such, the component can be configured to perform the task even when the component is not currently on. In general, the circuitry that forms the structure corresponding to "configured to" may include hardware circuits.

[0042] Various components may be described as performing a task or tasks, for convenience in the description. Such descriptions should be interpreted as including the phrase "configured to." Reciting a component that is configured to perform one or more tasks is expressly intended not to invoke 35 U.S.C. §112 paragraph (f), interpretation for that component.

[0043] The scope of the present disclosure includes any feature or combination of features disclosed herein (either explicitly or implicitly), or any generalization thereof, whether or not it mitigates any or all of the problems addressed herein. Accordingly, new claims may be formulated during prosecution of this application (or an application claiming priority thereto) to any such combination of features. In particular, with reference to the appended claims, features from dependent claims may be combined with those of the independent claims and features from respective inde-

pendent claims may be combined in any appropriate manner and not merely in the specific combinations enumerated in the appended claims.

[0044] It is to be understood the present invention is not limited to particular devices or biological systems, which may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting. As used in this specification and the appended claims, the singular forms "a", "an", and "the" include singular and plural referents unless the content clearly dictates otherwise. Thus, for example, reference to "a linker" includes one or more linkers.

DETAILED DESCRIPTION

Definitions

[0045] 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.

[0046] The term "compression" as used herein generally refers to the application of balanced inward (e.g., "pushing") forces to different points on a material or structure.

[0047] The term "connected" as used herein generally refers to pieces which may be joined or linked together.

[0048] The term "coupled" as used herein generally refers to pieces which may be used operatively with each other, or joined or linked together, with or without one or more intervening members.

[0049] The term "directly" as used herein generally refers to one structure in physical contact with another structure, or, when used in reference to a procedure, means that one process effects another process or structure without the involvement of an intermediate step or component.

[0050] The term "engine" as used herein generally refers to a machine designed to convert one form of energy into mechanical energy (e.g., electric motors, sonic wave generators, etc.).

[0051] The phrase "oscillation force" as used herein generally refers to a vibrational force, or a vibrational wave effect or wave form.

[0052] The term "pressure" as used herein generally refers to a force applied substantially perpendicular to a surface of an object.

Portable High Frequency Physiological Oscillator

[0053] Chest physiotherapy with bronchial drainage is a known treatment for mobilization and removal of airway secretions in many types of respiratory dysfunction especially in chronic lung disease (e.g., cystic fibrosis, bronchiectasis, bronchitis, primary ciliary dyskinesia syndrome). Chest physiotherapy has been demonstrated to be effective in maintaining pulmonary function and prevention or reduction of respiratory complications in patients with chronic respiratory diseases. In some embodiments, a system and/or method may include clearing a biological airway. Biological airways may include any portion of the respiratory system including, but not limited to, trachea, bronchi, bronchioles, and alveoli.

[0054] The method may include positioning a wearable system on a subject. The method may include adjusting the wearable system such that an oscillation force is applied to at least a first zone and to at least a second zone of the subject (e.g., and possibly more zones). In some embodiments, an oscillation force may include a vibrational force, or a vibrational wave effect or wave form.

[0055] FIG. **1** depicts a front perspective view of a representation of an embodiment of a portable high frequency chest wall oscillator system **100**. Known HFCWO systems do not allow for a user adjusting where forces are applied to on the subject. This is problematic because although some known HFCWO systems may come in different sizes to accommodate differently sized subjects, there are far too many people of different sizes and so it is impractical to produce enough differently sized systems for all of the differently sized subjects. FIG. **2** depicts a front view of a representation of an embodiment of a pair of human lungs **200**. Known HFCWO systems may typically apply forces at zones **210***a-b*. A system **100** may allow for adjusting where forces are applied to the subject, for example, to what are identified as at least the first zone **220***a* and the second zone **220***b*. Applying high frequency forces to zones **220** as opposed to zones **210** may allow for greater remediation of symptoms associated with certain forms of chronic lung disease.

[0056] In some embodiments, the first zone **220***a* may be proximate to and below a collarbone of the subject (e.g., as depicted in FIG. **2**). FIG. **2** depicts a front view of a representation of an embodiment of a pair of human lungs **200**. In some embodiments, the second zone **220***b* may be positioned below first zone and proximate to and above a bottom of a rib cage of the subject (e.g., as depicted in FIG. **2**). In some embodiments, the first and/or second zone may be positioned relative to any relevant markers (e.g., one or more of the subject's physiological markers) which results in increased mobilization of secretions in an airway within the subject. The method may include applying a force (e.g., an oscillation force, a high frequency force, a pneumatic force, etc.) to the first zone and/or the second zone (e.g., and possibly additional zones) using a first engine **110***a* and a second engine **110***b* respectively. The method may include mobilizing secretions in an airway within the subject (e.g., substantially adjacent the first and/or second zone). In some embodiments, an engine may include electric motors, sonic wave generators, etc.

[0057] In some embodiments, mobilizing secretions may include generating increased airflow velocities and/or percussive or oscillation forces resulting in cough-like shear forces. In some embodiments, mobilizing secretions may include decreasing a viscosity of at least some secretions in an airway within the subject substantially adjacent the first and/or second zone. Mobilizing secretions may assist subjects to move retained secretions from smaller airways to larger airways where they may move more easily via coughing. In some embodiments, secretions may include what is generally referred to as mucus. Mucus may include water, ions, soluble mediators, inflammatory cells, and/or secreted mucins. In some embodiments, secretions may include any fluids (e.g., excessive fluids) potentially blocking subject airways.

[0058] In some embodiments, adjusting the wearable system may include adjusting fastening systems which couple the wearable system to the subject. In some embodiments, the wearable system may be adjustable at least across a chest and/or portion of a torso of a subject (e.g., as depicted in FIG. **1** using friction fittings and straps **120**). In some embodiments, the wearable system may be adjustable at least across one or more shoulders of a subject (e.g., as depicted in FIG. **1**). In some embodiments, the wearable system may be adjustable using one or more fasteners **130** using at least one

type of fastener. In some embodiments, adjusting the wearable system may include positioning the first engine or the second engine (e.g., and possibly additional engines) relative to the first zone or the second zone (e.g., and possibly additional zones) respectively. In some embodiments, a fastener may include a plurality of snaps **130** coupling the wearable system across the shoulder of a subject (e.g., as depicted in FIG. **1**) such that the engines may positioned appropriately relative to the airways of the subject. By attaching the fasteners in different combinations with one another the engines may be adjusted relative to the subject.

[0059] In some embodiments, engines may be repositioned or adjusted relative to a subject using a system (e.g., by a doctor) which inhibits a subject from repositioning the engines once positioned. For example, a wearable garment may include a plurality of pockets or containers which engines may be positioned in and then sealed in. FIG. **6** depicts a front perspective view of a representation of an embodiment of a wearable system **100** using a plurality of sealable containers **190** coupling system used to couple the engines to the wearable system.

[0060] In some embodiments, the system may include a wearable system (e.g., as depicted in FIG. **1**) which resembles a vest (e.g., coupled or directly attached at least across a front, side, and/or back). In some embodiments, the system may include a wearable system which includes a plurality of bands and/or straps **160** (e.g., as depicted in FIG. **3**). FIG. **3** depicts a front perspective view of a representation of an embodiment of a portable high frequency chest wall oscillator harness **100**. In some embodiments, the bands **160** (e.g., as depicted in FIG. **3**) may be incorporated into a vest (e.g., as depicted in FIG. **1**). The engines **110***a-d* may be coupled or directly attached to the bands. The engines may be coupled or directly attached to the bands such that the engines are positionable along the bands. The bands may include vertical bands **160***a* and horizontal bands **160***b*. Positionable engines may allow the engines to be positioned appropriately to provide the greatest benefit to the subject.

[0061] The engines may be positionally coupled or directly attached to the bands and/or system using a number of means known such that the engines may be repositioned during use as appropriate for individual subjects. In some embodiments, a hook and loop system may be used to couple the engines to a wearable system such that the engines are repositionable. FIG. **5** depicts a front perspective view of a representation of an embodiment of a wearable system **100** using a hook and loop system to couple engines **100** to the system. In some embodiments, a cleat **170** may be used to couple the engine to one or more of the bands. FIG. **4**A depicts a front view of a representation of an embodiment of an engine coupling system **170**. FIG. **4**B depicts a side view of a representation of an embodiment of an engine coupling system **170**. The cleat may include a locking mechanism **180** which once locked may inhibit movement of the cleat along the band(s). In some embodiments, a coupling mechanism may couple a horizontal band **160***b* to a vertical band **160***a* such that engines are repositioned relative to the subject by repositioning the bands relative to one another. The bands may include coupling mechanisms as depicted in FIG. **1** in order to couple the bands to a subject. The lengths of the bands may be adjustable as well in order to fit the bands to the subject.

[0062] In some embodiments, the wearable system **100** may include multiple engines **110** (e.g., eight or more engines). The system may include at least four engines **110**, at least six engines **110**, or at least eight engines **110** (e.g., as depicted in FIG. **1**, although only the front four are depicted, the remaining four are on the back of the system **100**). In some embodiments, the system may include eight engines. In some embodiments, the method may include adjusting the wearable system comprises positioning a third engine or a fourth engine relative to the first zone or the second zone respectively on an opposing side of the subject opposite of the side of the first and the second engine.

[0063] In some embodiments, the system **100** may include a control unit **140**. The method may include activating at least the first engine using the control unit **140**. The control unit may control activation/deactivation/adjustment of all of the engines of the system **100**. In some embodiments, the control unit **140** may be couplable to the system **100** (e.g., using a flap of material which may be used to cover and protect the control unit as depicted in FIG. **1**). The control unit **140** may be directly wired to the engines **110** and/or may be wirelessly coupled or directly attached to the engines. The control unit may use any number of known input methods (e.g., including touchpad). The control unit may be digital or analog. In some embodiments, the control unit may adjust one or more settings of the engines. The control unit may adjust the oscillation force output by the engine. The control unit may adjust an amplitude of the oscillation force output by the engine. The control unit may adjust a frequency of the oscillation force output by the engine. In some embodiments, engine parameters may be adjusted via software (e.g., a phone app) remotely (e.g., Wi-Fi, Bluetooth, etc.). In some embodiments, the engines **110** may include a frequency range from 5 Hz to 20 Hz. In some embodiments, the intensity levels dictate the frequency which generally runs at 5 Hz for the lowest setting, 13 Hz for the medium setting and 20 Hz for the highest setting.

[0064] In some embodiments, a method may include modifying the treatment parameters (e.g. amplitude, frequency, and time for each engine). Each engine may be programmed, using physical hardware control unit or software to run a custom cycle. This programming may be performed by the subject. In addition, the system may provide a physician or caregiver with the ability to prescribe a defined treatment and to inhibit the user from modifying the treatment settings (e.g. lock-out feature w/ password, pin code, etc.).

[0065] In some embodiments, the method and/or system may adaptively modify the treatment protocol based on subject and/or physician feedback. For example, a subject enters mucus secretion levels after each treatment and the system adaptively optimizes the treatment settings over time.

[0066] In some embodiments, the method and/or system may monitor compliance for each subject, including parameters run, time of treatment, information. For example, the system could monitor (in real-time) the treatment time of day and any subject feedback. This could be accomplished through hardware or software (e.g. a web-based subject/physician portal which links w/Bluetooth to each vest). The information may be provided to the subject, physician, insurance company or other third-party.

[0067] In some embodiments, the system **100** may include at least one battery **150**. The method may include powering at least the first engine **110***a* using one or more batteries **150** coupled or directly attached to the wearable system. In some embodiments, a battery **150** may include a rechargeable battery and/or a disposable battery. The battery **150** may include two or more batteries. The batteries **150** may be easily

swapped out whether rechargeable or disposable. The battery **150** may be coupled or directly attached to the system **100** (e.g., using a flap of material which may be used to cover and protect the battery as depicted in FIG. **1**). The system may include an adapter such that when necessary the system may be coupled or directly attached to an electrical outlet (e.g., through an electrical adapter if necessary). The system **100** may be powered using AC or DC power sources such that the system may be powered using virtually any known power source currently available.

[0068] In some embodiments, the system may be self-contained. The system may be self-contained such that a subject may wear the system **100** and move freely and in a substantially unrestricted manner. The system may be self-contained such that a subject may wear the system **100** while functioning and not physically connected to any external devices (e.g., air pumps).

Upper Chest Portable High Frequency Physiological Oscillator

[0069] In some embodiments, a system and/or method may include clearing a biological airway(s). As discussed though even wearable systems as described herein may not be sufficient to assist a subject in fully clearing the subject's biological airway. In some instances secretions may be moved out of the lungs but not high enough into the major bronchial tubes and/or trachea such that a subject may evacuate the secretions from the subject (especially with the reduced air capacity of the subject who need to employ systems as described herein). It would be beneficial to have a system which works alone or in combination with the vest/harnesses described herein to further move a subject's secretions out of the subject's airways.

[0070] In some embodiments, the method may include positioning a wearable system around a subject's neck. The wearable system may be coupled or directly attached to another wearable garment such that the wearable system is positioned substantially around at least a portion of the subject's neck. The method may include adjusting the wearable system such that an oscillation force is applied to at least an upper first zone of the subject. The upper first zone may be proximate to a collarbone of the subject and proximate to a juxtaposition of the subject's bronchial tubes and trachea on a first side of the subject. The method may include applying the oscillation force to at least upper first zone using an upper first engine. The method may include mobilizing at least some secretions in an airway within the subject substantially adjacent the first zone so that it may be expelled by the subject.

[0071] FIG. **7** depicts a representation of an embodiment of a portable high frequency physiological oscillator harness **300** positioned around a subject's neck **400**. In some embodiments, the upper first engine **310** may include one or more engines. The engines may be separately powered and/or controlled. The upper first engine may include at least three engines **310***a-c*. In some embodiments, a first **310***a* of the three engines may be positioned proximate a first bronchial tube **410***a* extending from the juxtaposition. A second **310***b* of the three engines may be positioned proximate a second bronchial tube **410***b* extending from the juxtaposition. A third **310***c* of the three engines may be positioned proximate the trachea **420**. Positioning at least one (e.g., three) engine in such a fashion may assist a subject in clearing secretions out of the subject's airways, especially when used in combination with the vest/harness described herein. The vest/harness described herein may assist in moving secretions from a subject's airways in the lungs up into the at least major bronchial passages adjacent/in the upper first zone wherein the wearable system may further move the subject's secretions out of the subject.

[0072] In some embodiments, the method may include adjusting the wearable system such that the oscillation force is applied to at least an upper second zone of the subject. The upper second zone may be proximate to the collarbone of the subject and proximate to the juxtaposition of the subject's bronchial tubes and trachea. The upper second zone may be positioned on a second side of the subject, wherein the second side is on an opposing side of the subject from the first side. The method may include applying the oscillation force to the at least upper second zone using an upper second engine. The upper second engine may include at least one (e.g., three) engines.

[0073] In some embodiments, the wearable system **300** may include adjustable fastening systems **320** which couple the wearable system to the subject. Adjustable fastening systems may include snaps buckles, Velcro, etc. FIG. **8** depicts a representation of an embodiment of a portable high frequency physiological oscillator harness positioned around a subject's neck in combination with portable high frequency chest wall oscillator vest. The wearable system **300** may be used in combination with other systems which function to mobilize internal lung secretions. The wearable system **300** may be used without any other systems in order to mobilize internal lung secretions such that the secretions are expelled out of the subject.

[0074] In some embodiments, the system **300** may include a control unit **140** (e.g., a control unit of the system **300** may function independently of other possible control units, a control unit of the system **300** may be electrically coupled or directly attached to the control unit of the vest when used in combination with the vest, or the system **300** may not include an independent control unit and the system **300** may be coupled or directly attached into a control unit of a wearable system **100**). The method may include activating at least the upper first engine using the control unit **140**. The control unit may control activation/deactivation/adjustment of all of the engines of the system **300**. In some embodiments, the control unit **140** may be couplable to the system **300** (e.g., using a flap of material which may be used to cover and protect the control unit). The control unit **140** may be directly wired to the engines **310** and/or may be wirelessly coupled or directly attached to the engines. The control unit may use any number of known input methods (e.g., including touchpad). The control unit may be digital or analog. In some embodiments, the control unit may adjust one or more settings of the engines. The control unit may adjust the oscillation force output by the engine. The control unit may adjust an amplitude of the oscillation force output by the engine. The control unit may adjust a frequency of the oscillation force output by the engine. In some embodiments, engine parameters may be adjusted via software (e.g., a phone app) remotely (e.g., Wi-Fi, Bluetooth, etc.). In some embodiments, the engines **310** may include a frequency range from 5 Hz to 20 Hz. In some embodiments, the intensity levels dictate the frequency which generally runs at 5 Hz for the lowest setting, 13 Hz for the medium setting and 20 Hz for the highest setting.

[0075] In some embodiments, a method may include modifying the treatment parameters (e.g. amplitude, frequency,

and time for each engine). Each engine may be programmed, using physical hardware control unit or software to run a custom cycle. This programming may be performed by the subject. In addition, the system may provide a physician or caregiver with the ability to prescribe a defined treatment and to inhibit the user from modifying the treatment settings (e.g. lock-out feature w/password, pin code, etc.).

[0076] In some embodiments, the method and/or system may adaptively modify the treatment protocol based on subject and/or physician feedback. For example, a subject enters mucus secretion levels after each treatment and the system adaptively optimizes the treatment settings over time.

[0077] In some embodiments, the method and/or system may monitor compliance information. For example, the system could monitor (in real-time) the treatment for each subject, including parameters run, time of treatment, time of day and any subject feedback. This could be accomplished through hardware or software (e.g. a web-based subject/physician portal which links w/Bluetooth to each vest). The information may be provided to the subject, physician, insurance company or other third-party.

[0078] In some embodiments, the system **300** may include at least one battery **150** (e.g., a battery of the system **300** may function independently of other possible batteries, a battery of the system **300** may be electrically coupled or directly attached to the battery of the vest when used in combination with the vest, or the system **300** may not include an independent battery and the system **300** may be coupled or directly attached into a battery of a wearable system **100**). The method may include powering at least the upper first engines **310** using one or more batteries **150** coupled or directly attached to the wearable system. In some embodiments, a battery **150** may include a rechargeable battery and/or a disposable battery. The battery **150** may include two or more batteries. The batteries **150** may be easily swapped out whether rechargeable or disposable. The battery **150** may be coupled or directly attached to the system **300** (e.g., using a flap of material which may be used to cover and protect the battery). The system may include an adapter such that when necessary the system may be coupled or directly attached to an electrical outlet (e.g., through an electrical adapter if necessary). The system **300** may be powered using AC or DC power sources such that the system may be powered using virtually any known power source currently available.

[0079] In some embodiments, the system may be self-contained. The system may be self-contained such that a subject may wear the system **300** and move freely and in a substantially unrestricted manner. The system may be self-contained such that a subject may wear the system **300** while functioning and not physically connected to any external devices (e.g., air pumps).

Positionable Oscillating Motor Array with Potentially Disposable and/or Recyclable Portions

[0080] In some embodiments, it is advantageous to form a wearable system with one or more disposable portions. There are many advantages to having a wearable system formed from at least in part disposable portions including facilitating use of the wearable system in different environments (e.g., hospitals, clinics, etc.). Professional healthcare environments are required to constantly be vigilant regarding sanitation and cross contamination between patients. To this end medical equipment must be sanitized before being used again. However, sanitizing equipment is typically time consuming and/or expensive. As such much of the equipment used in healthcare environments which comes into direct contact with subjects is disposable (or covered by disposable sheaths). It is typically much easier and/or less expensive to throw away equipment which comes into contact with subjects as opposed to cleaning the equipment.

[0081] The method may include positioning a wearable system on a subject. The method may include adjusting the wearable system such that an oscillation force is applied to at least a first zone and to at least a second zone of the subject (e.g., and possibly more zones). In some embodiments, the oscillation force may be infinitely adjustable relative to the subject. Having an infinitely adjustable oscillation force (e.g., infinitely positionable engines) may allow customizable positioning of the oscillation force as required by the subject (e.g., as prescribed by a care giver (e.g., doctor, nurse, etc.).

[0082] In some embodiments, mobilizing secretions may include generating increased airflow velocities and/or percussive or oscillation forces resulting in cough-like shear forces. In some embodiments, mobilizing secretions may include decreasing a viscosity of at least some secretions in an airway within the subject substantially adjacent the first and/or second zone. Mobilizing secretions may assist subjects to move retained secretions from smaller airways to larger airways where they may move more easily via coughing. In some embodiments, secretions may include what is generally referred to as mucus. Mucus may include water, ions, soluble mediators, inflammatory cells, and/or secreted mucins. In some embodiments, secretions may include any fluids (e.g., excessive fluids) potentially blocking subject airways.

[0083] Depending upon the subject's specific condition one or more engines may be positioned accordingly (e.g., around the area of trouble for the subject which require treatment). FIGS. **9**A-J depict representations of different areas of a subject's lungs **510***a-b* which may require treatment using herein described systems and methods. FIGS. **9**A-J depict representations of right lung **510***a* and left lung **510***b* of subject **500**. Zones **520** of lungs **510** are examples of areas in a subject which may need treatment and/or wherein treatment may be applied as prescribed by a physician for treatment. FIGS. **9**A-J depict representations of subject **500** positioned for extracting fluids from lungs **510** using known percussion methods. In some embodiments, positioning the subject **500**, as depicted in FIGS. **9**A-J for example, may be used in combination with the systems and methods described herein. In some embodiments, any special positioning of the subject may not be necessary and/or used in combination with the systems and methods described herein. FIG. **9**A depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the left and right anterior apical portions of lungs **510**. FIG. **9**B depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the left and right posterior apical portions of lungs **510**. FIG. **9**C depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the left and right anterior segments of lungs **510**. FIG. **9**D depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the right middle lobe portion of lung **510**. FIG. **9**E depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and

methods described herein) respiratory afflictions affecting the left singular portion of lung **510**. FIG. **9**F depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the left and right anterior basil portions of lungs **510**. FIG. **9**G depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the right lateral basal portion of lung **510**. FIG. **9**H depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the left lateral basal portion of lung **510**. FIG. **9**I depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the left and right posterior basal portions of lungs **510**. FIG. **9**J depicts subject **500** positioning and/or zones **520** for treating (e.g., applying oscillation forces using systems and methods described herein) respiratory afflictions affecting the left and right superior basal portions of lungs **510**. FIGS. **9**A-J depict representations of how systems described herein may be used as examples of prescriptive positioning of engines by a caregiver.

[0084] FIG. **10** depicts a front perspective view of a representation of an embodiment of a portable high frequency chest wall inner harness **610** of an oscillator system **600**. Known HFCWO systems do not allow for a user adjusting where forces are applied to on the subject. This is problematic because although some known HFCWO systems may come in different sizes to accommodate differently sized subjects, there are far too many people of different sizes and so it is impractical to produce enough differently sized systems for all of the differently sized subjects. A system **600** which allows for adjustment and/or positioning of one or more engines and/or one or more groups of engines may allow for prescriptive oscillation or prescriptive positioning of engines by a caregiver. For example, a caregiver may employ means to visualize (e.g., x-rays) secretions accumulating in the lungs of a subject and then position engines appropriately around any areas where secretions are accumulating. In some embodiments, engines may not only be simply placed adjacent treatment areas but also may be positioned adjacent to areas adjacent to the treatment area to assist in flushing out secretions from the subject (e.g., pushing the secretions outside of the subject). In some embodiments, engines may be positioned in a serpentine pattern on a subject using systems described herein to create what may be described as a wave effect of oscillation forces.

[0085] In some embodiments, a caregiver may prescribe not only the position of the engines but also the frequency of one or more of the engines. The pulse or the beat frequency of one or more of the engines may be adjusted based upon a prescribed frequency. In some embodiments, a caregiver may prescribe or program one or more or all of the engines to turn on or off.

[0086] FIG. **10** depicts a front perspective view of a representation of an embodiment of a portable high frequency chest wall inner (or first) harness **610** of an oscillator system **600**. In some embodiments, inner harness **610** may be sold in multiple sizes (e.g., 3 or more sizes). The inner harness may be sold in 3 sizes (e.g., child size, small adult size, large adult size). In some embodiments, an inner harness may be custom made or sized for a subject. In some embodiments, the inner harness may be formed from a flexible, a pliable or non-rigid material (e.g., as depicted in FIGS. **10-17** and **18-25**). A pliable material may allow the inner harness to fit a wider range of differently physically sized subjects. The flexible material may allow the inner harness to bunch up around a slighter framed subject once cinched up. As such an inner wearable system may initially hang loosely in some embodiments.

[0087] In some embodiments, adjusting the wearable system inner harness may include adjusting fastening systems which couple the wearable system to the subject. In some embodiments, the wearable system may be adjustable at least across a chest and/or portion of a torso of a subject (e.g., as depicted in FIGS. **10**, **10-17** and **18-23** using friction fittings and straps **620**). In some embodiments, the wearable system may be adjustable at least across one or more shoulders of a subject (e.g., as depicted in FIGS. **1**, **10-17** and **18-23**) or one or more sides of a chest of a subject or a coupling system in a front of a subject (e.g., using zippers or lacing). In some embodiments, the wearable system may be adjustable using one or more fasteners. In some embodiments, the inner harness may include few or no size adjusting fasteners (e.g., as depicted in FIGS. **24-25**).

[0088] In some embodiments, the inner harness may include a positioning system **630**. The positioning system **630** may include a coupling method including, for example, a hook and loop coupling system which allows for positioning and coupling one or more portions of the oscillator system **600** to the inner harness. In some embodiments, a coupling method may include straps or pockets (e.g., as depicted in FIG. **6**) used to position engines or other portions of the oscillator system **600**.

[0089] In some embodiments, engines may be repositioned or adjusted relative to a subject using a system (e.g., by a doctor) which inhibits a subject from repositioning the engines once positioned.

[0090] The engines may be positionally coupled or directly attached to the bands and/or system using a number of means known such that the engines may be repositioned during use as appropriate for individual subjects. In some embodiments, a hook and loop system may be used to couple the engines to a wearable system such that the engines are repositionable. FIGS. **10-11** depict a front view and a rear view respectively of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness **610** positioned on a subject. The embodiment depicted in FIGS. **10-11** includes positioning system **630** wherein the positioning system includes a plurality of hook and loop strips **630** for coupling portions of the oscillating system (e.g., engines **640**, controller **650**, battery **660**, etc.) to the inner harness. The strips **630** depicted are just an example of a pattern of how the strips may be distributed on the harness. Specifically the strips may be positioned on the inner harness to allow positioning engines around the treatment areas as for example as depicted in FIGS. **9**A-J.

[0091] In some embodiments, positioning system may include all (or substantially all) of the exterior surface of the inner harness (e.g., as depicted in FIGS. **10-15**) being formed from half of a hook and loop system such that engines of the system **600** are virtually unlimited, in relation to the inner harness, as to where the portions may be positioned (the exterior surface may include a second layer formed from half of a hook and loop system). FIGS. **12-13** depict a front view and a rear view respectively of a representation of an embodi-

ment of a portable high frequency chest wall oscillator inner harness positioned on a subject including a second layer **610***a* coupled or directly attached to the inner harness. In some embodiments, positioning system may include all (or substantially all) of the interior surface of the inner harness (e.g., as depicted in FIGS. **16-25**) being formed from half of a hook and loop system such that engines of the system **600** are virtually unlimited, in relation to the inner harness, as to where the engines may be positioned (the interior surface may include a second layer formed from half of a hook and loop system). FIGS. **16-25** depict various views of a representation of an embodiment of a portable high frequency chest wall oscillator inner harness including a plurality of engines positioned on an interior surface of the inner wearable system.

[0092] In some embodiments, they system **600** may include an outer (or second) harness **680** (e.g., as depicted in FIGS. **14-15** and **20-25**). The outer harness **680** may be positionable around at least a portion of an exterior of the inner harness **610**. The outer harness may be formed from an elastic, a stretchable or flexible material which when worn compresses or applies pressure or a force or a compressive force to the inner harness and more importantly to any engines beneath the outer harness. Applying pressure to the engines may increase the efficiency of the engines as regards the treatment areas by pressing the engines against the subject. Generally the outer harness may function, during use, to improve transmission of the oscillation force from the engines to the treatment area of the subject. The outer harness may function to further adjust the oscillation force based upon how tightly around the subject the outer harness is secured. The outer harness may function to provide a compressive force based upon how tightly around the subject the outer harness is secured. The outer harness functions to, in some embodiments, gather and/or tighten an inner harness around a subject to provide at least a better fit. In some embodiments, a system may include a single outer wearable harness (e.g., as depicted in FIGS. **20-21**). In some embodiments, a system may include two or more outer wearable harnesses (e.g., as depicted in FIGS. **22-25**). In some embodiments, a system may include two or more outer wearable harnesses wherein the outer wearable harnesses **680***a-b* are different widths (e.g., as depicted in FIG. **26**).

[0093] The outer harness may allow for fewer sizes of the inner harness to be made available as the outer harness functions to tighten the engines against the subject such that the inner harness does not need to fit as snugly. A first end of the outer harness may couple to a second end of the outer harness and/or to another portion of the outer harness during use (e.g., using hook and loop, buckles, clasps, etc.). At least a portion of the outer harness may be coupled or directly attached (e.g., permanently fixed (either directly (e.g., sewn to) or indirectly) or temporarily fixed (either directly (e.g., sewn to **690** as depicted in FIG. **25**) or indirectly)) to the inner harness. At least a portion of the outer harness may be coupled or directly attached to the inner harness in such a way as to allow movement in one or more directions of the outer harness relative to the inner harness (e.g., a double slit cut into the inner wearable harness through which the outer wearable harness is threaded through allowing latitudinal and/or longitudinal movement). In some embodiments, one or more portions of the outer wearable harness may be coupled or directly attached to the inner wearable harness using elongated members or loops **700** allowing the outer wearable harness to move relative to the inner harness while remaining coupled or directly attached to the inner wearable harness. The loops may allow a subject to more easily access the outer wearable harnesses during use (allowing the subject to more easily reach the outer wearable harnesses).

[0094] In some embodiments, the outer harness may include any way of providing a compressive force to against one or more of the engines increasing the efficiency of the oscillating force applied to the subject during use (e.g., an outer harness which laces up, tightening buckles, etc.). This is in contrast to some currently known vests which are rigid, wherein the rigidity of the vest controls the placement of the engines during use.

[0095] In some embodiments, one or more engines or portions of the system may be positioned (e.g., coupled or directly attached to) the outer harness (e.g., to an inner and/or outer surface of the outer harness).

[0096] In some embodiments, the wearable system **600** may include multiple engines **640** (e.g., two or more engines, for example, as depicted in FIG. **10**). The system may include at least four engines **640**, at least six engines **640**, at least eight engines **640** or as many engines as necessary (e.g., as prescribed by a physician). In some embodiments, an engine **640** (e.g., as depicted in FIGS. **18**A-B) may include electric motors, sonic wave generators, electro-mechanic or electro-dynamic vibrators, solenoid, etc. In some embodiments, engines **640** may be positioned in containers **645** (e.g., as depicted in FIG. **24**). Containers **645** may be formed from primarily flexible or pliable materials. The container may include fixation means (e.g., hook and loop) which allow for positioning the engines **640** as necessary relative to system **600**. The containers may substantially contain the engines **640** using a zipper and/or a closure flap with a button or hook and loop. In some embodiments, one or more containers may include padding (e.g., or be formed from a thicker pliable material). Padded containers may diffuse the oscillation force (e.g., vibration force) over a broader area of a subject, for example, to protect a subject from unintentional injury. The containers may be disposable, for example, for the purpose of controlling infection (e.g., after use discard the containers and reuse the engines. Containers may also be used for batteries and/or controllers. In some embodiments, engines, controllers, and/or batteries may be saved for reuse and/or recycling. In some embodiments, an engine **640** (e.g., as depicted in FIG. **18**C) may include a substantially smooth outer covering such that the engine is easier disinfect the engine before and/or after use.

[0097] In some embodiments, the system **600** may include a control unit **650** (e.g., as depicted in FIGS. **11**, **16**, **19-23**, and **25**). The method may include activating at least the first engine using the control unit **650**. The control unit may control activation/deactivation/adjustment of all of the engines of the system **100**. In some embodiments, the control unit **650** may be couplable to the inner harness **610** (e.g., using a hook and loop strip **630** as depicted in FIG. **11** or positioned in a pocket as depicted in FIG. **25**). The control unit **650** may be directly wired to the engines **640** and/or may be wirelessly coupled or directly attached to the engines. The control unit may use any number of known input methods (e.g., including touchpad). The control unit may be digital or analog. In some embodiments, the control unit may adjust one or more settings of the engines. The control unit may adjust the oscillation force output by the engine. The control unit may adjust an amplitude of the oscillation force output by the engine. The control unit may adjust a frequency of the oscillation force

output by the engine. In some embodiments, engine parameters may be adjusted via software (e.g., a phone app) remotely (e.g., Wi-Fi, Bluetooth, etc.).

[0098] In some embodiments, the engines **110** may include a frequency range from 5 Hz to 20 Hz. In some embodiments, the intensity levels dictate the frequency which generally runs at 5 Hz for the lowest setting, 13 Hz for the medium setting and 20 Hz for the highest setting. In some embodiments, engines may be grouped together such that frequencies produced by the grouped engines result in a superposition of the produced frequencies in order to achieve frequencies and/or intensities not achievable under normal operating parameters of the engines. For example a superpulse may be achievable, lower frequencies may be achievable. The ability to produce such a variety of different frequencies is beneficial for treating different types of lung disorders. The principle of superposition may be applied to waves whenever two (or more) waves travel through the same medium at the same time. The waves pass through each other without being disturbed. The net displacement of the medium at any point in space or time, is simply the sum of the individual wave displacements. This is true of waves pulses or continuous sine waves. For example, two sinusoidal waves with the same amplitude and frequency can add either destructively or constructively depending on their relative phase. The phase difference between the two waves may increase with time so that the effects of both constructive and destructive interference may be seen. When the two individual waves are exactly in phase the result is large amplitude. When the two waves become exactly out of phase the sum wave is zero.

[0099] For example, bronchiectasis is a condition in which damage to the airways causes them to widen and become flabby and scarred preventing the airways from clearing mucus (mucus which is typically voluminous and relatively thin). In contrast cystic fibrosis is a genetic disorder that results in at least difficulty breathing and an inability to clear the lungs of mucus (mucus which is typically relatively thick). Different conditions result in different mucus and/or debris in a subject's lungs which may benefit from different frequencies which may be prescribed by, for example, a physician.

[0100] In some embodiments, a method may include modifying the treatment parameters (e.g. amplitude, frequency, and time for each engine). Each engine may be programmed, using physical hardware control unit or software to run a custom cycle. This programming may be performed according to each subject. In addition, the system may provide a physician or caregiver with the ability to prescribe a defined treatment and/or to inhibit the user from modifying the treatment settings (e.g. lock-out feature w/password, pin code, etc.). Each of the motors may be individually programmable (e.g., length of run time, type of vibration (e.g., constant, pulsing, etc.), frequency, amplitude, etc.).

[0101] In some embodiments, the method and/or system may adaptively modify the treatment protocol based on subject and/or physician feedback. For example, a subject enters mucus secretion levels after each treatment and the system adaptively optimizes the treatment settings over time.

[0102] In some embodiments, the method and/or system may monitor compliance information. For example, the system could monitor (in real-time) the treatment for each subject, including parameters run, time of treatment, time of day and any subject feedback. This could be accomplished through hardware or software (e.g. a web-based subject/physician portal which links w/Bluetooth to each vest). The information may be provided to the subject, physician, insurance company or other third-party.

[0103] In some embodiments, the system **600** may include at least one battery **660**. The method may include powering the engines **640** using one or more batteries **660** coupled or directly attached to the inner harness of the wearable system. In some embodiments, a battery **660** may include a rechargeable battery and/or a disposable battery. The battery **660** may include two or more batteries. The batteries **660** may be easily swapped out whether rechargeable or disposable. The battery **660** may be coupled or directly attached to the system **600** (e.g., using a hook and loop strip **630** as depicted in FIG. **11**). The system may include an adapter such that when necessary the system may be coupled or directly attached to an electrical outlet (e.g., through an electrical adapter if necessary). The system **100** may be powered using AC or DC power sources such that the system may be powered using virtually any known power source currently available.

[0104] In some embodiments, the system **600** may include a system of electrical couplings **670**. Electrical couplings **670** may couple control unit **650** and/or battery **660** to engines **640** (e.g., as depicted in FIGS. **10-13**). The electrical couplings may run on an exterior surface of the inner harness (e.g., as depicted in FIGS. **10-11**). The electrical couplings may run under a second layer **610***a* of inner harness **610** (e.g., as depicted in FIGS. **12-13**) with coupling ends extending out of openings in the second layer **610***a*. In some embodiments, at least some portions of the electrical couplings may be bound or bundled together (e.g., such that the electrical couplings are easier to separate from the rest of the system **600** for disposal or recycling. In some embodiments, the electrical couplings (e.g., wires) may be sewn in to the disposable inner wearable system. The inner wearable system may include conduits **675** (e.g., fabric, impervious materials (e.g., plastics) as depicted in FIG. **24**) for wires coupled or directly attached to and/or sewn into the inner wearable system (e.g., to electrically connect a battery and/or a controller to at least one of the plurality of engines). In some embodiments, conduits **675** may be positionable relative to the inner wearable system. The conduits may be connected to the inner wearable system using hook and loop systems. The wires may provide multiple connection points for the plurality of engines so that the plurality of engines are repositionable while still using the wires in the fabric conduits.

[0105] In some embodiments, the system may be self-contained. The system may be self-contained such that a subject may wear the system **600** and move freely and in a substantially unrestricted manner. The system may be self-contained such that a subject may wear the system **600** while functioning and not physically connected to any external devices (e.g., air pumps).

[0106] In some embodiments, all, substantially all, or at least one portion of the system **600** may be disposable or recyclable. Making portions of the system **600** disposable may be disposable due to, for example, that much of the equipment used in healthcare environments which comes into direct contact with subjects is disposable (or covered by disposable sheaths). It is typically much easier and/or less expensive to throw away equipment which comes into contact with subjects as opposed to cleaning the equipment. In some embodiments, the inner wearable harness is disposable. In some embodiments, the outer wearable harness is disposable. In some embodiments, at least some of the plurality of

engines are disposable. In some embodiments, the inner and/or outer harness and the engines may be disposable.

[0107] In some embodiments, one or more portions of the system **600** are recyclable. For example self-contained portions of the system (e.g., engines **640**) may be recyclable in order to reduce waste.

[0108] In some embodiments, one or more portions of the systems describe herein may include antimicrobial coatings (e.g, in fabrics of the vests). In some embodiments, one or more portions of the systems described herein may be able to withstand one or more common medical sterilization techniques (e.g., high temperature, high pressure, chemical, etc.). In some embodiments, one or more portions (e.g, in fabrics of the vests or the containers for one or more engines) may include an impervious materials, coatings, or linings such that one or more portions of the system are protected from or at least inhibited from exposure to one or more contaminants. For example, a lining or material may be substantially impervious to water or blood borne pathogens or contaminants. For example, a lining or material may be substantially impervious to gasses and/or air borne pathogens or contaminants. In some embodiments, a container such as a positionable engine container **645** may include an impervious or impermeable lining which inhibits contamination of an engine positioned in the container such that the engine may be more easily recycled.

[0109] In this patent, certain U.S. patents, U.S. patent applications, and other materials (e.g., articles) have been incorporated by reference. The text of such U.S. patents, U.S. patent applications, and other materials is, however, only incorporated by reference to the extent that no conflict exists between such text and the other statements and drawings set forth herein. In the event of such conflict, then any such conflicting text in such incorporated by reference U.S. patents, U.S. patent applications, and other materials is specifically not incorporated by reference in this patent.

[0110] Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as the presently preferred embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed, and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description of the invention. Changes may be made in the elements described herein without departing from the spirit and scope of the invention as described in the following claims.

1.-164. (canceled)

165. A system, comprising:

a inner wearable system worn, during use, on a torso of a subject, wherein the inner wearable harness is a flexible vest comprising an opening for a head of the subject, and openings for arms of the subject;

a plurality of engines which when activated apply an oscillation force to at least one treatment area of the subject, wherein the oscillation force mobilizes, during use, at least some secretions in an airway within the subject at least adjacent the treatment area; and

a flexible container for containing at least one of the plurality of engines, wherein the flexible container is releasably couplable to the inner wearable system such that the at least one of the plurality of engines is selectively positionable relative to the subject using a positioning system, wherein the positioning system allows positioning the flexible container such that the oscillation force is applied to at least one of the treatment areas of the subject, and,

an outer wearable system worn, during use, on a torso of a subject, wherein the outer wearable system, when activated, adjusts the oscillation force applied by at least some of the activated plurality of engines to the treatment area by providing a compressive force.

166. The system of claim **165**, further comprising wires sewn in to the inner wearable system configured to electrically connect a battery and/or a controller to at least one of the plurality of engines.

167. The system of claim **165**, further comprising fabric conduits for wires sewn in to the inner wearable system configured to electrically connect a battery and/or a controller to at least one of the plurality of engines, wherein the wires provide multiple connection points for the plurality of engines so that the plurality of engines are repositionable while still using the wires in the fabric conduits.

168. The system of claim **165**, wherein the flexible container is releasably couplable to an interior surface the inner wearable system, wherein the interior surface is positioned adjacent the subject when worn by the subject.

169. The system of claim **165**, wherein the outer wearable harness comprises two stretchable elongated bands coupled to the inner wearable harness, and wherein a first portion of the outer wearable harness is couplable to a second portion of the outer wearable harness.

170. The system of claim **165**, wherein the flexible container comprises a liner which is positionable, during use, in the flexible container, and wherein the liner is positionable, during use, in the flexible container.

171. The system of claim **165**, wherein the flexible container comprises a liner which is substantially impermeable to at least some contaminants.

172. The system of claim **165**, wherein the flexible container comprises a liner which is substantially impermeable to water soluble contaminants.

173. The system of claim **165**, wherein the flexible container comprises a liner which is substantially impermeable to blood and blood soluble contaminants.

174. The system of claim **165**, wherein the inner wearable system worn comprises a fastening system adjacent the opening for the head of the subject which allows for placement of the inner wearable system on the subject.

175. A method of clearing a biological airway, comprising:

positioning an inner wearable system on a torso of a subject, wherein the inner wearable harness is a flexible vest comprising an opening for a head of the subject, and openings for arms of the subject;

containing an engine in a flexible container;

selectively positioning at least some of a plurality of flexible containers on and/or adjacent at least one treatment area, wherein at least one of the plurality of flexible containers is releasably couplable to the inner wearable harness such that the at least one of the plurality of flexible containers is positionable relative to the subject using a positioning system;

positioning an outer wearable system on a torso of a subject;

applying an oscillation force to at least one of the treatment areas using at least some of the plurality of engines;

adjusting the oscillation force to at least some of the activated plurality of engines to the treatment area by providing a compressive force by activating the outer wearable harness; and

mobilizing at least some secretions in an airway within the subject substantially adjacent the at least one treatment zone.

176. The method of claim **175**, further comprising electrically connecting a battery and/or a controller to the engine using wires sewn in to the inner wearable system.

177. The method of claim **175**, further comprising electrically connecting a battery and/or a controller to the engine using fabric conduits for wires sewn in to the inner wearable system, wherein the wires provide multiple connection points for the engine so that the engine is repositionable while still using the wires in the fabric conduits.

178. The method of claim **175**, wherein the flexible container is releasably couplable to an interior surface the inner wearable system, wherein the interior surface is positioned adjacent the subject when worn by the subject.

179. The method of claim **175**, wherein the outer wearable harness comprises two stretchable elongated bands coupled to the inner wearable harness, and wherein a first portion of the outer wearable harness is couplable to a second portion of the outer wearable harness.

180. The method of claim **175**, further comprising positioning the engine in a liner and positioning the liner in the flexible container.

181. The method of claim **175**, wherein the flexible container comprises a liner which is substantially impermeable to at least some contaminants.

182. The method of claim **175**, wherein the flexible container comprises a liner which is substantially impermeable to water soluble contaminants.

183. The method of claim **175**, wherein the flexible container comprises a liner which is substantially impermeable to blood and blood soluble contaminants.

184. The method of claim **175**, wherein the inner wearable system worn comprises a fastening system adjacent the opening for the head of the subject which allows for placement of the inner wearable system on the subject.

185. (canceled)

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(54) **LOW FREQUENCY LUNG VIBRATION AND SPUTUM REMOVAL APPARATUS**

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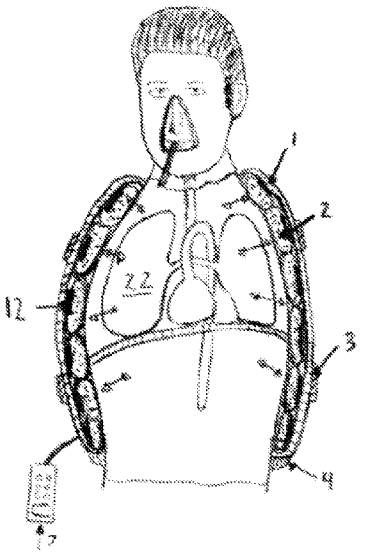
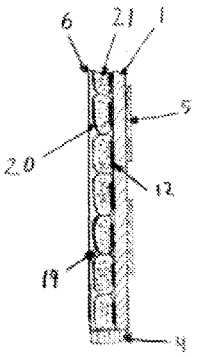
(57) **ABSTRACT**

A low-frequency lung vibration apparatus is designed to vibrate lungs clogged by sputum, using acoustic waves. The freed sputum becomes easier to be removed by expectoration. The apparatus includes a garment composed of layers, a plurality of electro-mechanical or dynamic vibrators and a controlling unit. An inner layer contains a loading and shape conforming material, while an outer shell holds the vibrators, the controller and the inner garment together. An outer shell is made of a non-stretch material. Several fasteners/zippers hold the inner garment in place and several strategically placed straps allow a tight fit of the garment. The loading created by the layers of the apparatus is tailored to cause the existence of a uniform compression-expansion resonance of the lungs beneficial for sputum removal. A controlling unit allows the detection of a person's lungs resonance frequency and controls the vibrator(s) frequency and amplitude during a treatment.





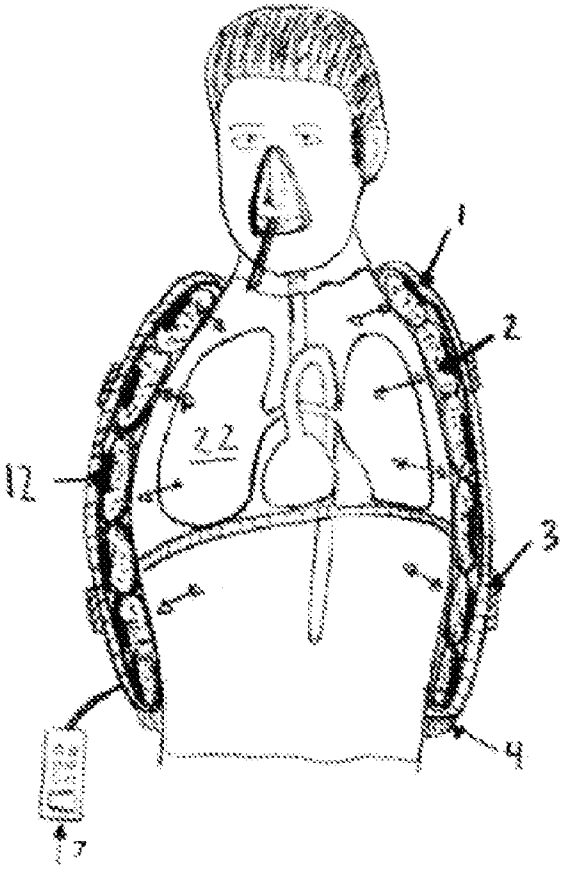


Figure 1

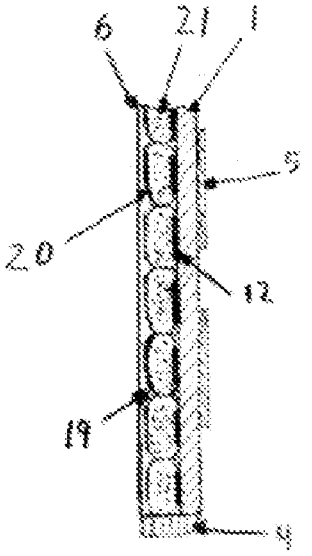
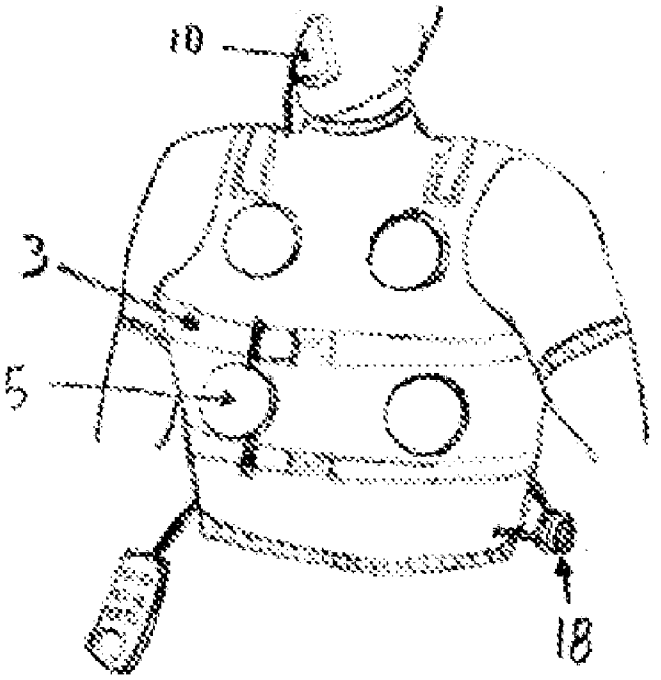


Figure 2



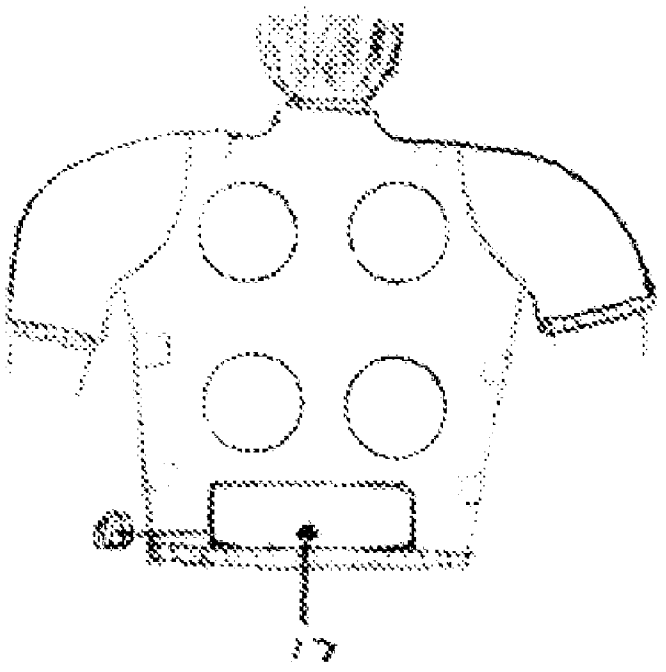


Figure 3

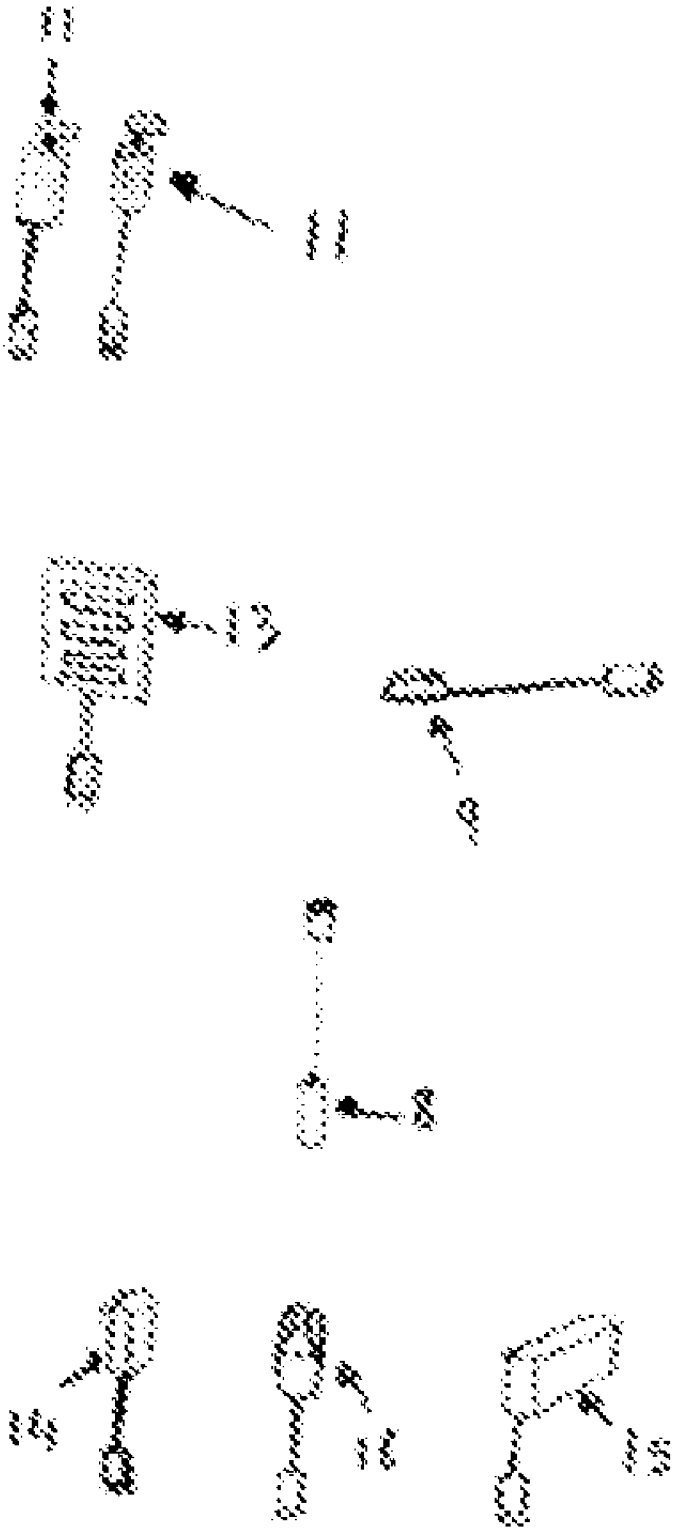


Figure 4

LOW FREQUENCY LUNG VIBRATION AND SPUTUM REMOVAL APPARATUS

PARENT CASE TEXT

[0001] This non-provisional patent application is a continuation of provisional patent application Ser. No. 67/733,285 filed on Nov. 3, 2005.

TECHNICAL FIELD

[0002] The present invention relates generally to therapeutic treatments for medical patients, and, more particularly, to an apparatus for causing the mobilization of respiratory secretions through the acoustic excitation of the lungs at or near their compression and expansion resonance frequency. This acoustic excitation and resulting vibration helps to dislodge, loosen and expectorate the sputum from the lungs of a person.

BACKGROUND OF THE INVENTION

[0003] Cystic Fibrosis (CF) is a recessive genetic disease caused by mutations in a membrane-associated protein, which promotes transcellular movement of chloride ions in airway epithelia and other tissues. In the lungs, defective function of the membrane-associated protein results in abnormally thick secretions in the lower airways which plug small bronchioles and provide an environment for chronic endobronchincal bacterial infection. Despite recruitment of vast numbers of neutrophils, bacterial clearance is ineffective, and the airways of the lungs are damaged by free radical species and prostheses released by the neutrophils. In addition, as the recruited neutrophils decompose in the airway, the DNA from their nuclei markedly increase the viscosity of the lower airway secretions, leading to further airway blockage and infection. The end result of this above-identified cycle is destruction of bronchial airway structure and progressive loss of lung function in the CF patient. Despite significant improvements in clinical management, respiratory failure and related pulmonary complications account for over ninety percent of CF mortality.

[0004] Since pulmonary disease is the primary cause of morbidity and mortality in CF, considerable effort has been directed to increase the mobilization of the abnormally thick airway secretions through various forms of chest physiotherapy. In the normal respiratory system, there are three primary mucus transport mechanisms. First, as is predominate in the smaller airways of the lungs, is a conveyor-like effect of a coordinated beating of airway epthocilia. In the larger airways, the second method of mucus transport is the high velocity airflow associated with coughing. Coughing tends to shear mucus off airway surfaces and propels it towards the pharynx. The third mechanism of transporting mucus through the lungs is termed cephalad airflow bias of tidal breathing. Cephalad airflow bias results from greater expiratory versus inspiratory airflow due to compression of the intrathorasic airways during expiration. However, the abnormal composition and increased amount of tracheal bronchial secretions in the airways of a CF patient impede all of these natural mechanisms of mucus clearance.

[0005] For this reason, several forms of chest physiotherapy have been developed. These methods of chest physiotherapy are intended to assist in pulmonary mucus clearance and are presently widely used for CF patients. The mechanism underlying all modes of chest physiotherapy currently in use is vibration of the airway surfaces, either through the external chest compression or by oscillatory airflow, to promote increased cephalad-induced and/or cough-induced mobilization of airway secretions.

[0006] Currently, the most common form of chest physiotherapy is manual chest physiotherapy. In manual chest physiotherapy a trained caregiver strikes the patient's chest with cupped hands. This striking motion is usually complimented with postural drainage, a systematic form of directing mucus from the peripheral to the central airways through a series of gravity-assisted patient positions and therapist stimulation. Each physiotherapy session is coupled with a period of huffing and coughing to remove sputum. While this method of therapy is somewhat effective, manual chest physiotherapy is labor intensive and may require the skill of a trained caregiver. For this reason, manual chest physiotherapy may be expensive and/or time consuming for the therapist and patient. Additionally, the striking of the chest may cause discomfort to the patient or damage to a more fragile patient's ribcage.

[0007] Various mechanical devices have been developed in an effort to standardize and increase the efficiency of chest physiotherapy. Among the most widely employed forms of mechanical chest physiotherapy are various hand-held compressors which deliver external chest vibration, devices such as a FLUTTER™ device, U.S. Pat. No. 5,018,517 by Liardet, which delivers internal airway stimulation from pulsating airflow via the mouth, and high frequency chest compression administered through an inflatable jacket. These mechanical devices actually compress the external chest wall resulting in physically compressing the ribs, muscles and lungs. These devices typically use air bladders that are inflated and deflated by motor-operated air valves, as described in U.S. Pat. No. 5,056,505 by W. J. Warwick and L. G. Hansen. The external vibration of the chest has also been obtained by various types of electro-magnetic sources, as described in U.S. Pat. No. 5,235,967 by Arbisi and in U.S. Pat. No. 6,193,678 by Brannon.

[0008] The high frequency chest compression (HFCC) method of chest physiotherapy is very commonly employed today. HFCC is administered via a product called the VEST™. In clinical studies with CF patients, use of the VEST™ has been shown to be a practical, automated method of chest physiotherapy, and is an improvement over manual therapy to the extent that it allows for increased patient independence. HFCC, via oscillating chest compression, stimulates cough with its associated mucus shearing airflow spikes, and the compression of the thorax during expiration results in increased expiratory airflow. It is hypothesized also that HFCC at certain frequencies promotes a longer ciliary brush stroke, thereby enhancing mucus transport.

[0009] The VEST™ device consists of an inflatable vest structure which is strapped onto the patient's torso. The inflatable vest structure is attached by supply tubes to an air compressor. The air compressor is powered such that it can force air into the vest worn by the patient at set frequencies and amplitudes. In this way, the vest that the patient wears is inflated to compress the patient's chest at set frequencies and amplitudes.

[0010] With the present mechanical devices such as the VEST™, the oscillating pressure administered to the chest wall is not transmitted equally across the chest to the underlying lung. Increased mucus transport only occurs in

those portions of the lungs directly covered by the VEST™. In particular, with the VEST™ device the lungs are excited from the sides but not from the top or bottom. The pressure administered by the VEST™ device is not uniform. The pressures applied to the patient's chest vary greatly. Additionally, the frequency at which the vest operates is not fine-tuned such as to optimize airway stimulation with the least amount of applied external energy. Generally, in clinical use of the VEST™, patients adjust the frequency and amplitude of the applied chest wall oscillation to what they believe provides the best results.

[0011] In addition to the above-referenced shortcomings of the prior art chest physiotherapy regimens, the current methods of chest physiotherapy are generally quite uncomfortable. Most of the current methods of chest physiotherapy require a force to be exerted on the external chest cavity of the patient. This is disadvantageous to all patients, but particularly to those who are more prone to rib or chest injury due to the impact, such as frail or elderly patients and very young patients.

[0012] Another type of device uses a water-filled bath and sound sources to generate sound waves aimed at dislodging the sputum stored in a person's lungs, as described by Nedwell in U.S. Pat. No. 6,190,337, or by Rogers in U.S. Pat. No. 6,974,425. While a patient is seated in a water-filled bath, the sound generated by the device interacts almost entirely with the lungs, but does not interact with the rest of the body because its acoustic impedance is similar to that of water. The presence of the surrounding water also causes a lung resonance where the lung expands and contracts uniformly at relatively large amplitudes. The drawbacks of this system include its lack of portability and the necessity to submerge the patient in a bulky water filled bath.

[0013] Therefore, it would be desirable to have a method and apparatus for chest physiotherapy that does not involve a trained caregiver or physiotherapist, such as to minimize cost, and also involves a marginal, if any amount of impact to the patient's chest. It is also desirable to have a method and apparatus for chest physiotherapy that does not cause discomfort to the patient, applies more uniform stimulation to the lungs and excites the entire lung. Finally it is desirable to have an apparatus which is portable. The invention described in detail below meets the limitations of the prior art.

SUMMARY OF THE INVENTION

[0014] The present invention aims to use the advantages of the previously cited therapies, but to forego their respective drawbacks.

[0015] The VEST™ developed by Warwick or Arbisi provides a portable means of self-treatment, which is its main advantage. Therefore our apparatus will be based on a portable unit. However, the treatment methodology offered Warwick or Arbisi is not the most efficient because it does not take into account the actual environment of the lungs and the interaction between the lung and the environment.

[0016] Sound and vibrations interact with the lungs much more efficiently if there is no impedance mismatch between the sound propagating media and the chest. This is a key advantage of the patent by Nedwell. Therefore our apparatus includes an inner layer composed of a form fitting material, like a gel or a fluid, which has approximately the same acoustic impedance as a body.

[0017] While seated in a water bath described by Nedwell or Rogers, the lungs are loaded by the water that surrounds them. This uniform loading of the lungs is required to be able to excite the lungs in a uniform compression-expansion manner. Therefore our apparatus will include a significant mass of a form fitting material and materials that surround it. The location of the mass loading is designed to compensate for the water-like mass already present in the stomach area of a person and create a uniform loading of a chest. Therefore a t-shirt, a jacket or a turtleneck shape will be favorite embodiments of an apparatus. Depending on the body shape and dimensions of a person, the load required to uniformly load the chest varies between 10 and 40 lbs. With such a load, the lung will have a resonance close both in frequency and mode shape (uniform expansion and compression) to the fundamental resonance observed in submerged divers ("Measurement of the depth dependent resonance of water loaded human lungs" J. S. Martin, P. H. Rogers, and E. A. Cudahy, Journal of the Acoustical Society of America 117. 2291-2300, 2005).

[0018] While uniformly loaded, a uniform compression-expansion resonance frequency of the lungs falls between 10 and 100 Hz depending on a person. In order to determine a lung resonance frequency of a person, a calibration is run. A sweep in frequency between 10 and 100 Hz is used in conjunction with a hydrophone, an accelerometer and/or an airflow measurement device. A resonance is determined as a frequency for which the Sound Pressure Level difference between a calibration with a suitable model and a calibration with a person wearing an apparatus is the highest, as measured by a hydrophone or an accelerometer. A resonance can also be defined as a frequency for which the airflow measured out of the nose and mouth of the wearer decreases drastically over a short frequency range.

[0019] Once a resonance frequency of a person's lungs has been established, a therapeutic level of treatment is between 150 and 170 dB re 1 μPa measured at the sternal notch. A hydrophone and/or an accelerometer are used during the treatment to monitor the acoustic level surrounding the lungs.

[0020] To ensure that the vibration created by the sources propagates mostly towards the chest of a person wearing the apparatus, several stiffened and weight-bearing areas are positioned on the outer shell. These areas are more rigid and denser than the average rigidity and density of the chest.

[0021] A treatment session usually lasts 30 minutes. It can be divided in segments of different length and frequency. For example, a treatment regimen could be 30 minutes at the detected resonance frequency. Another regimen could be divided in three sessions. One session lasts 10 minutes below the resonance frequency, 10 minutes at the resonance frequency and 10 minutes above the resonance frequency. The order of each session can be randomized.

[0022] The method and apparatus described herein can result in effective treatment of many debilitating ailments. For example, this method and apparatus may prove to be a particularly effective treatment for cystic fibrosis patients, chronic obstructive pulmonary disease, pneumonia, and lung cancer, by way of example.

[0023] This method is also an improvement over the prior art for several reasons. First it can be operated such that a lung of a patient moves uniformly for more effective treatment. Second, it creates and exploits a resonance which permits effective excitation with less driving energy and

force. Third, this method does not require the presence of a trained caregiver or physical therapist. Finally, it is common to administer drugs to patients, such as cystic fibrosis patients, through airborne inhalants. Experimental evidence suggests that the absorption of air-delivered drugs, if administered during acoustic excitation of the lungs, will increase.

[0024] Other systems, methods, features, and advantages of the present invention will be or become apparent to one with skill in the art upon examination of the following drawings and detailed description. It is intended that all such additional systems, methods, features, and advantages be included within this description, be within the scope of the present invention, and be protected by the accompanying claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The invention can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale, emphasis instead being placed upon clearly illustrating the principles of the present invention. Moreover, in the drawings, like reference numerals designate corresponding parts throughout the several views.

[0026] FIG. **1** is a cut-away front view of an exemplary low frequency lung vibration and sputum apparatus and of a chest according to the present invention.

[0027] FIG. **2** is a cut-away side view of the layers composing the low frequency lung vibration and sputum apparatus.

[0028] FIG. **3** is a front and back view of the low frequency lung vibration and sputum apparatus

[0029] FIG. **4** is an exemplary of the accessories of the low frequency lung vibration and sputum apparatus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0030] The apparatus can have several overall shapes. A turtleneck, a vest or a jacket can easily be envisioned, as depicted in the accompanying drawings. These drawings represent the unit invented for males. Different units, but based on the same concepts, are also envisioned to fulfill the specific requirements of a female or a child chest.

[0031] The excitation of the lungs (**22**) is obtained by classical electro-mechanic or electro-dynamic vibrators (**11**), which are commonly known by people in the field. Depending on the physiology of a person, the therapeutic acoustic level and uniformity requirements, more than one vibrator may be used.

[0032] Vibrators are located between an outer shell (**1**) of an apparatus and the chest of a person. They are attached to an apparatus via hook and loop fasteners, such as Velcro®, stitches or glue as commonly done in the field of chest message and vibration. When using hook and loop fasteners, the vibrator(s) can be attached in a most beneficial therapeutic position. An outer shell presents local reinforcements (**5**) which help with the loading of a chest and the stiffening of an apparatus.

[0033] An outer shell of an apparatus allows a tight fit of an inner layer (**2**) with a person's chest. This fit is obtained by tightening belts or Velcro covered straps (**3**) attached to an outer shell of an apparatus. A belt (**4**) is used to tighten an apparatus above a lower part of a person's abdomen.

[0034] An inner layer is composed of several enclosures made of washable packaging (**20**). Each enclosure contains a form fitting material, like a gel or a fluid (**21**). The quantity and location of a material is adapted to an individual in order to ensure a proper fit and a proper mass loading of a person's lung.

[0035] To provide a best fit of an inner layer, a pump (**18**) is used to fill an inner layer (**19**) with fluid from a reservoir (**17**) between an inner layer of an apparatus and the chest of a patient in a waterproof and flexible compartment (**6**).

[0036] An inner layer (**19**) can be connected to an outer shell with zippers, stitches or hook and loop fasteners (**12**), depending on the preferred embodiment of an apparatus.

[0037] Electric heating elements (**13**) can be added to an apparatus to help provide relief to a person.

[0038] An inner layer (**19**) can be foreseen as a cooling/heating unit if an inner layer is placed in a warm or cold environment before being worn.

[0039] A hand held controller (**7**) is connected to the vibrators of an apparatus, to a hydrophone (**8**), a accelerometer (**9**) and an airflow-meter (**10**). A hydrophone and an accelerometer are placed above the sternal notch, while the airflow-meter covers the nose and mouth of a person. A controller determines a compression/expansion resonance frequency of the lungs of a person by using inputs from the sensors connected to it. A controller also includes a timing mechanism to monitor the length of a treatment, and amplitude of the excitation.

[0040] The invention can be powered by an AC/DC converter (**14**), a rechargeable battery pack (**15**) or a vehicle cigarette lighter power adapter (**16**).

We claim:

1. A lung vibration and sputum removal apparatus comprising:

A vest unit including a flexible inner surface that fits tightly to a wearer's body, an intermediate layer containing a loading material, and an outer non-stretch surface with at least one reinforced or stiffened area;

at least one electro-dynamic or electro-mechanic vibration unit, located between an intermediate layer and an outer surface's reinforced area(s);

at least one heating pad unit, including a heating pad connecting jack, located between an inner surface and an outer surface;

a pump allowing an inner surface of an apparatus to fit a wearer's body contour;

a control unit including a control circuit housed within a control housing, a control circuit being in electrical connection with a control unit power input plug connectable to a power source; a vibration frequency and amplitude variable position control switch, a heating pad on/off switch, a heating pad heat intensity variable position heat control switch, and a wiring harness including at least a cable in connection between the control circuit and a vibration unit; a pump and a pump control switch used to fit the apparatus to a wearer's chest.

2. The apparatus of claim **1** wherein:

a lung is induced to vibrate at, or near, a resonance frequency.

3. The apparatus of claim **1**, wherein:

said system further includes a battery pack with a battery pack control unit connecting jack; and

said control unit power input plug is connectable with said battery pack control unit connecting jack.

4. The apparatus of claim **3** wherein:
said system further includes an AC/DC converter unit with a converter unit control unit jack; and
said control unit power input plug is connectable to said converter unit control unit jack.
5. The apparatus of claim **4** wherein:
said system further includes a vehicle cigarette lighter power adapter with an adapter control unit connecting jack; and
said control unit power input plug is connectable with said adapter control unit connecting jack.
6. The apparatus of claim **1** wherein:
said intermediate layer is composed of water.
7. The apparatus of claim **1** wherein:
said intermediate layer is composed of a gel with comparable acoustic impedance to water.
8. The apparatus of claim **1** wherein:
said intermediate layer is composed of a layer of water and a layer of a gel with comparable acoustic impedance to water.
9. The apparatus of claim **6** wherein:
a pump is used to displace water to insure the fit of the inner layer to a wearer's chest.
10. The apparatus of claim **8** wherein:
a pump is used to displace a layer of water and of a gel with comparable acoustic impedance to water to insure a fit of an inner layer to a wearer's chest.
11. The apparatus of claim **1** wherein:
said intermediate layer's mass distribution is used to load a lung uniformly.
12. The apparatus of claim **1** wherein:
said intermediate layer's mass distribution produces a load which simulates a user being submerged in water.
13. The apparatus of claim **1** wherein:
said outer layer holds hook and pile fasteners or elastomeric bands to fit an apparatus to a wearer's chest.
14. The apparatus of claim **1** wherein:
a control unit includes a microprocessor.
15. The apparatus of claim **14** wherein:
a microprocessor controls a vibration frequency and amplitude of a vibration unit(s).
16. The apparatus of claim **15** wherein:
a vibration frequency is varied between 10 and 100 Hz to determine a lung resonance frequency.
17. The apparatus of claim **16** wherein:
at least one hydrophone is placed on an inner layer of an apparatus and measures a local sound pressure level.
18. The apparatus of claim **17** wherein:
a hydrophone(s) and microprocessor are used to determine a lung resonance frequency between 10 and 100 Hz.
19. The apparatus of claim **18** wherein:
a microprocessor controls a vibration amplitude of a vibrating unit at a measured resonance frequency for a wearer defined length of time or for a factory defined length of time.
20. The apparatus of claim **14** wherein:
a microprocessor controls a vibration amplitude at a specified percent of a measured resonance frequency or at an increment relative to a wearer's resonance frequency.
21. The apparatus of claim **14** wherein:
an airflow meter is connected to a control unit.
22. The apparatus of claim **21** wherein:
an airflow meter is used to determine a lung resonance frequency.
23. The apparatus of claim **22** wherein:
a microprocessor controls a vibration amplitude of a vibrating unit at a measured resonance frequency for a wearer defined length of time or for a factory defined length of time.
24. The apparatus of claim **23** wherein:
a microprocessor controls the vibration amplitude at a specified percent of a measured resonance frequency or at an increment relative to a wearer's resonance frequency for a wearer defined length of time or for a factory defined length of time.
25. The apparatus of claim **14** wherein:
at least one accelerometer is connected to a control unit.
26. The apparatus of claim **25** wherein:
an accelerometer(s) is (are) used to determine a lung resonance frequency.
27. The apparatus of claim **26** wherein:
a microprocessor controls a vibration amplitude of a vibrating unit at a measured resonance frequency for a wearer defined length of time or for a factory defined length of time.
28. The apparatus of claim **27** wherein:
a microprocessor controls a vibration amplitude at a specified percent of a measured resonance frequency or at an increment relative to a wearer's resonance frequency for a wearer defined length of time or for a factory defined length of time.

* * * * *

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(54) **PORTABLE ARTICLE FOR ADMINISTERING THERAPY TO A USER**

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(72) Inventor: **Danny L. Nickelson**, Pacific, MO (US)

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(2), (4) Date: **Apr. 7, 2014**

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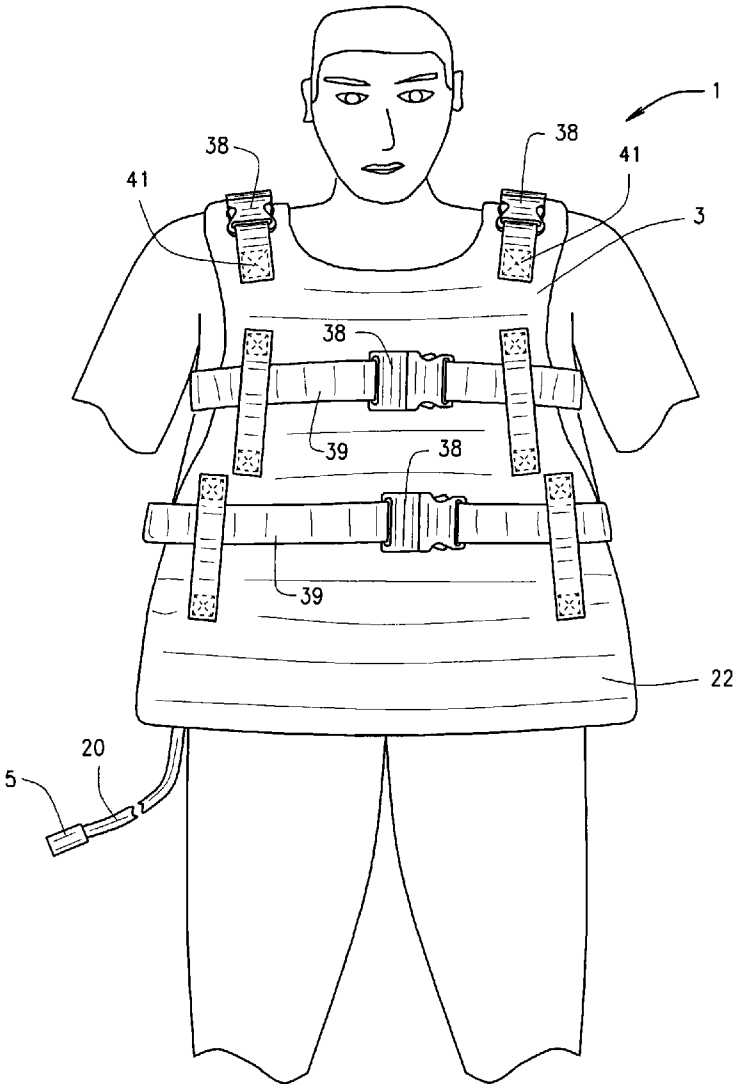
A61H 1/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A61H 1/008*** (2013.01)
USPC **601/150**

(57) **ABSTRACT**

A portable article for administrating therapy to a user includes a device positioned along the area of the body requiring therapy. At least one power pod is associated with the device and the power pod simultaneously applies a firs force component perpendicular to the user's body surface and a second force component parallel to the user's body surface. An illustrative embodiment is a vest worn by the user during therapy.



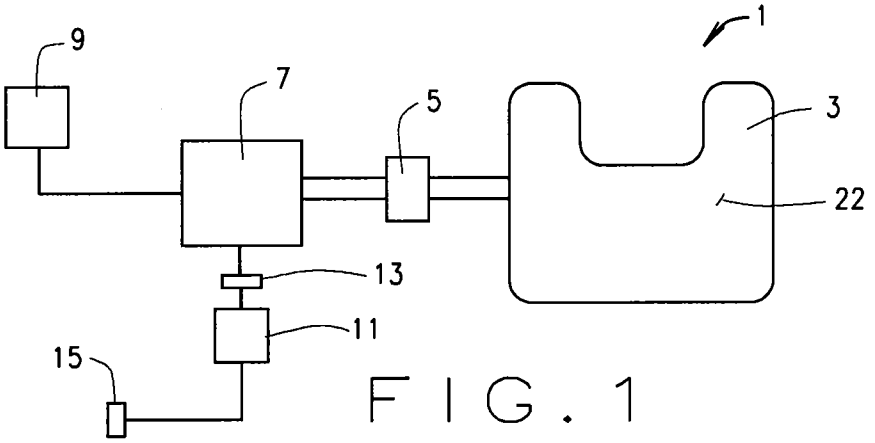


FIG. 1

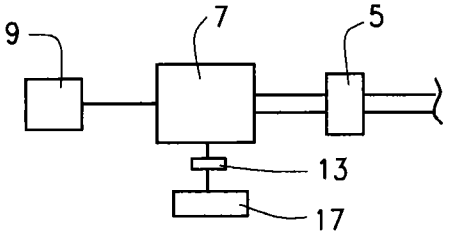


FIG. 1B

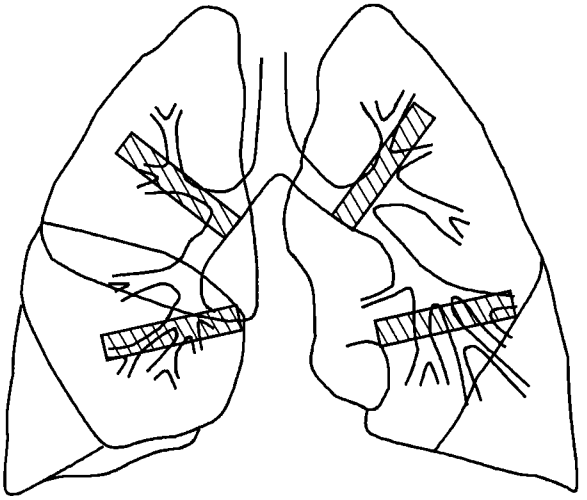


FIG. 2

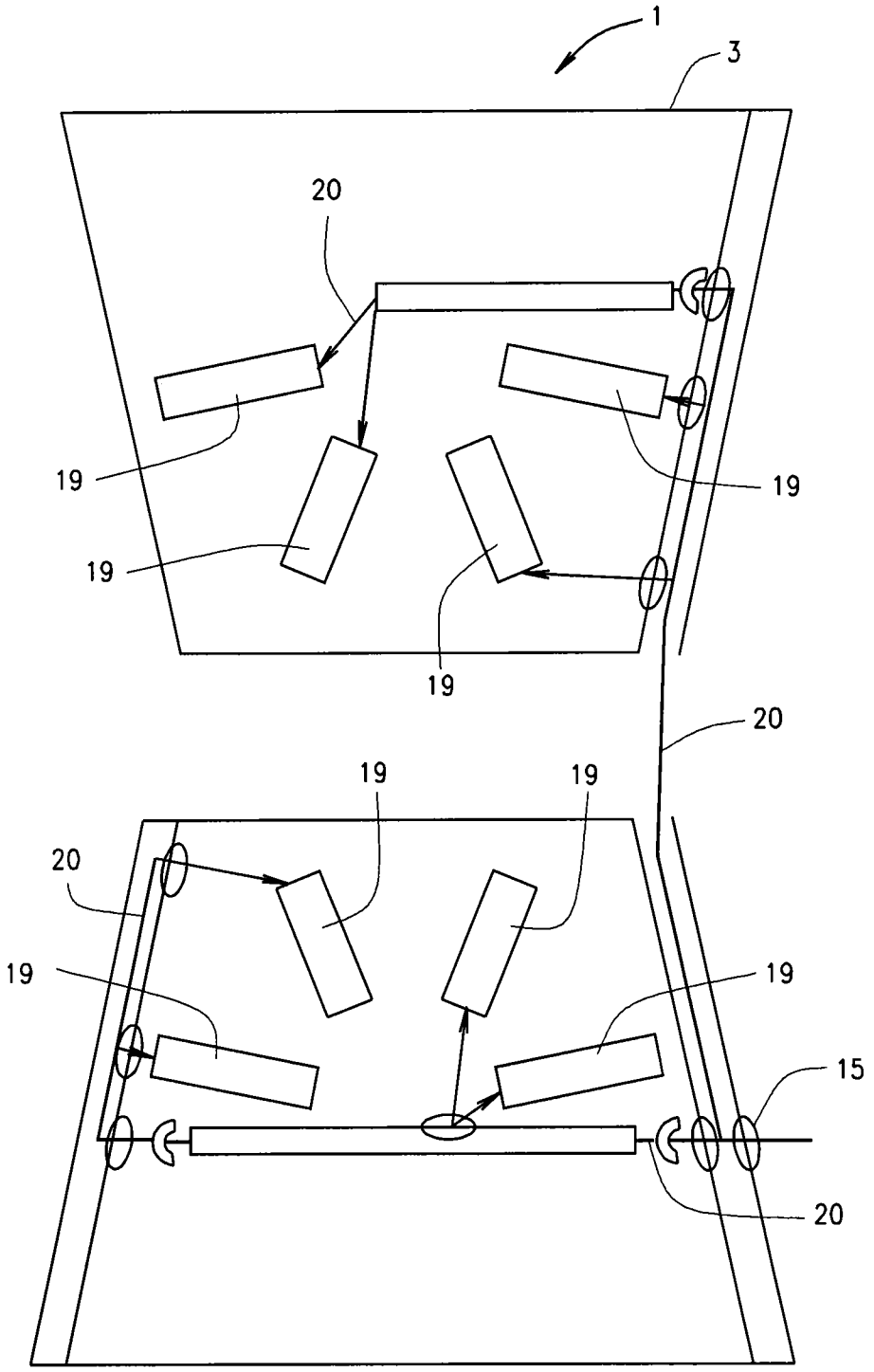


FIG. 3

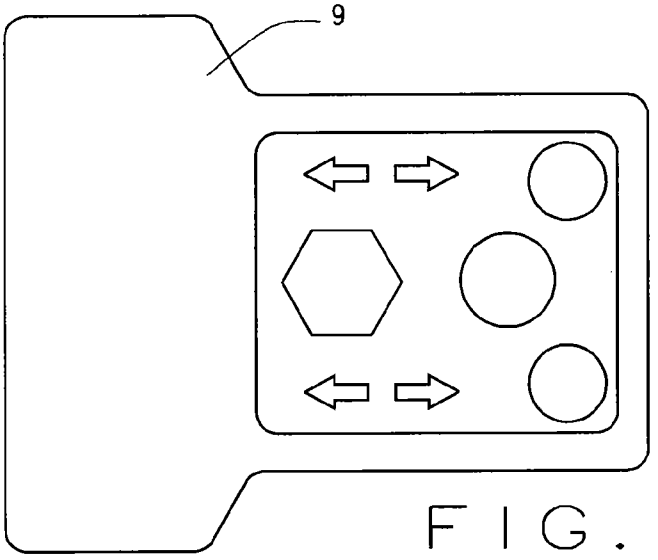


FIG. 4

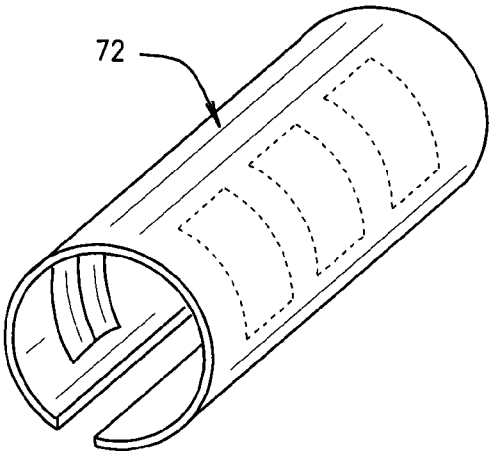


FIG. 5A

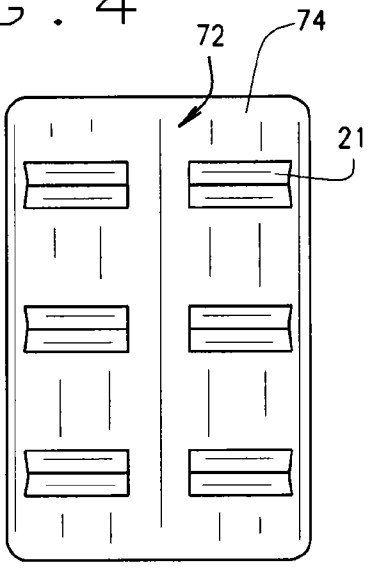


FIG. 5B

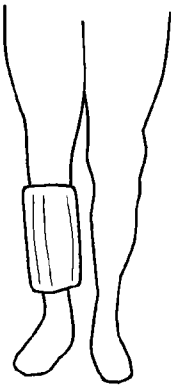


FIG. 5C

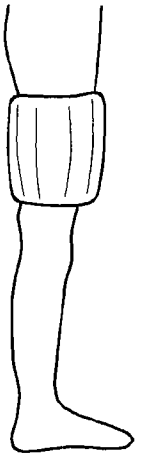


FIG. 5D

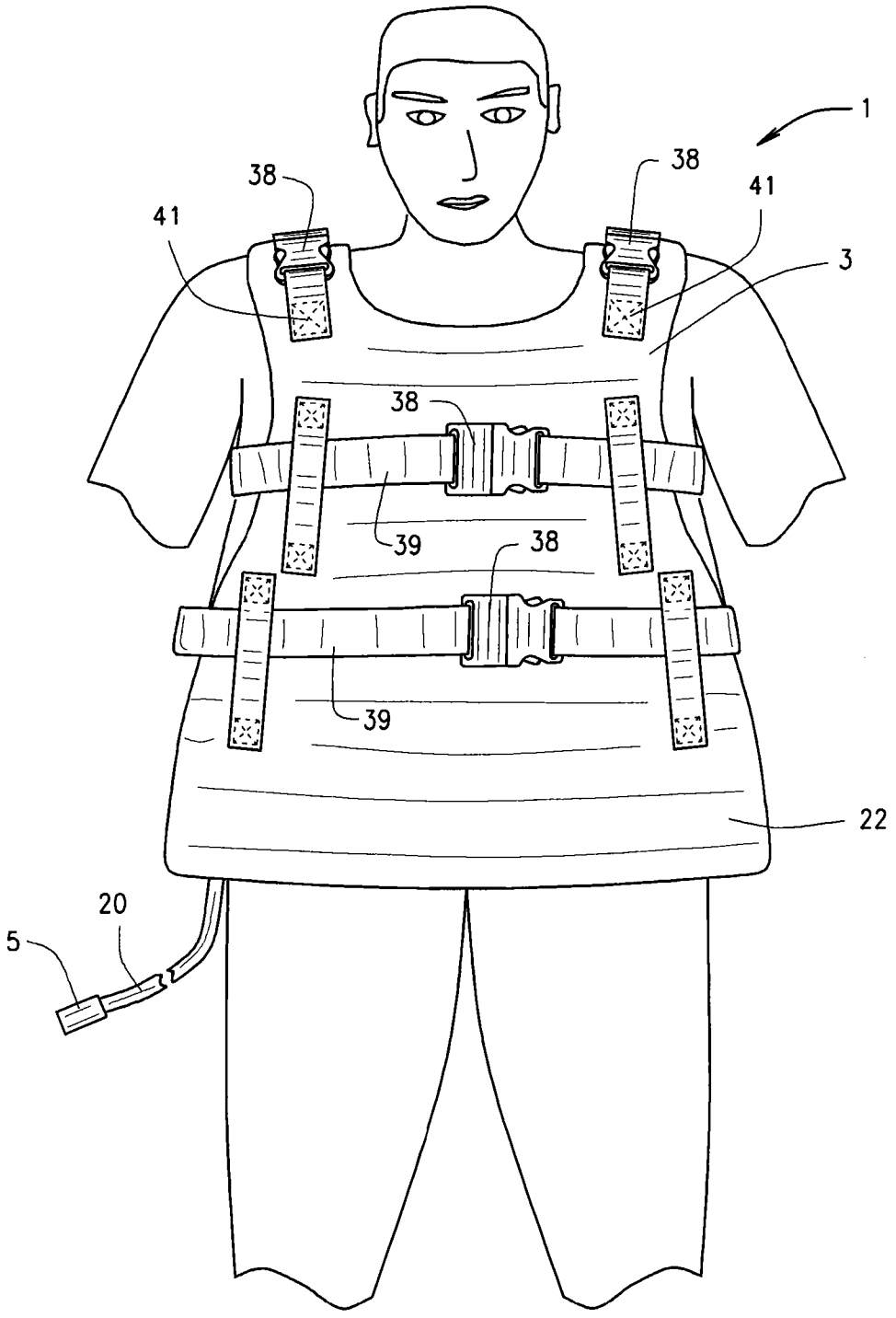


FIG. 6

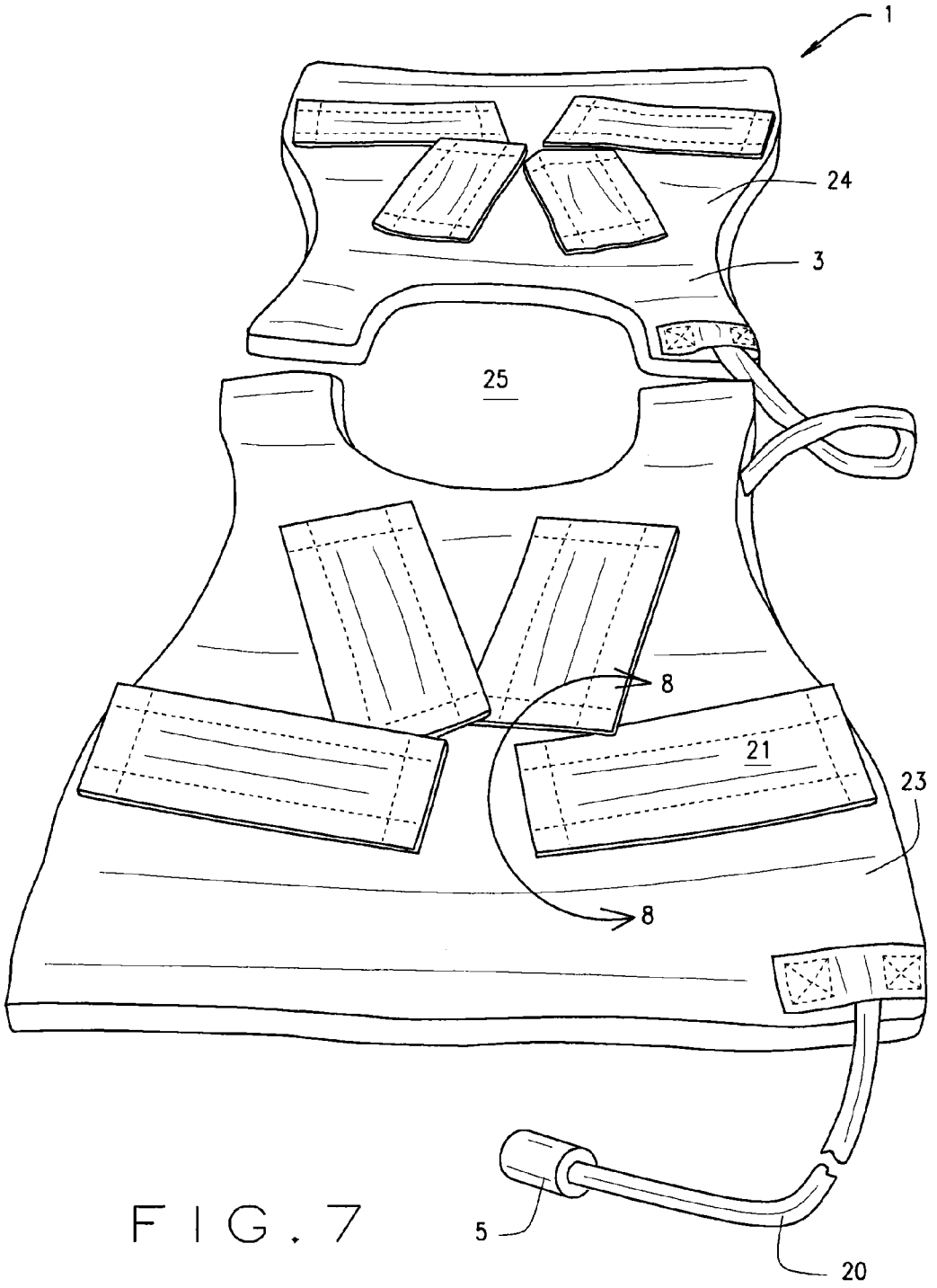


FIG. 7

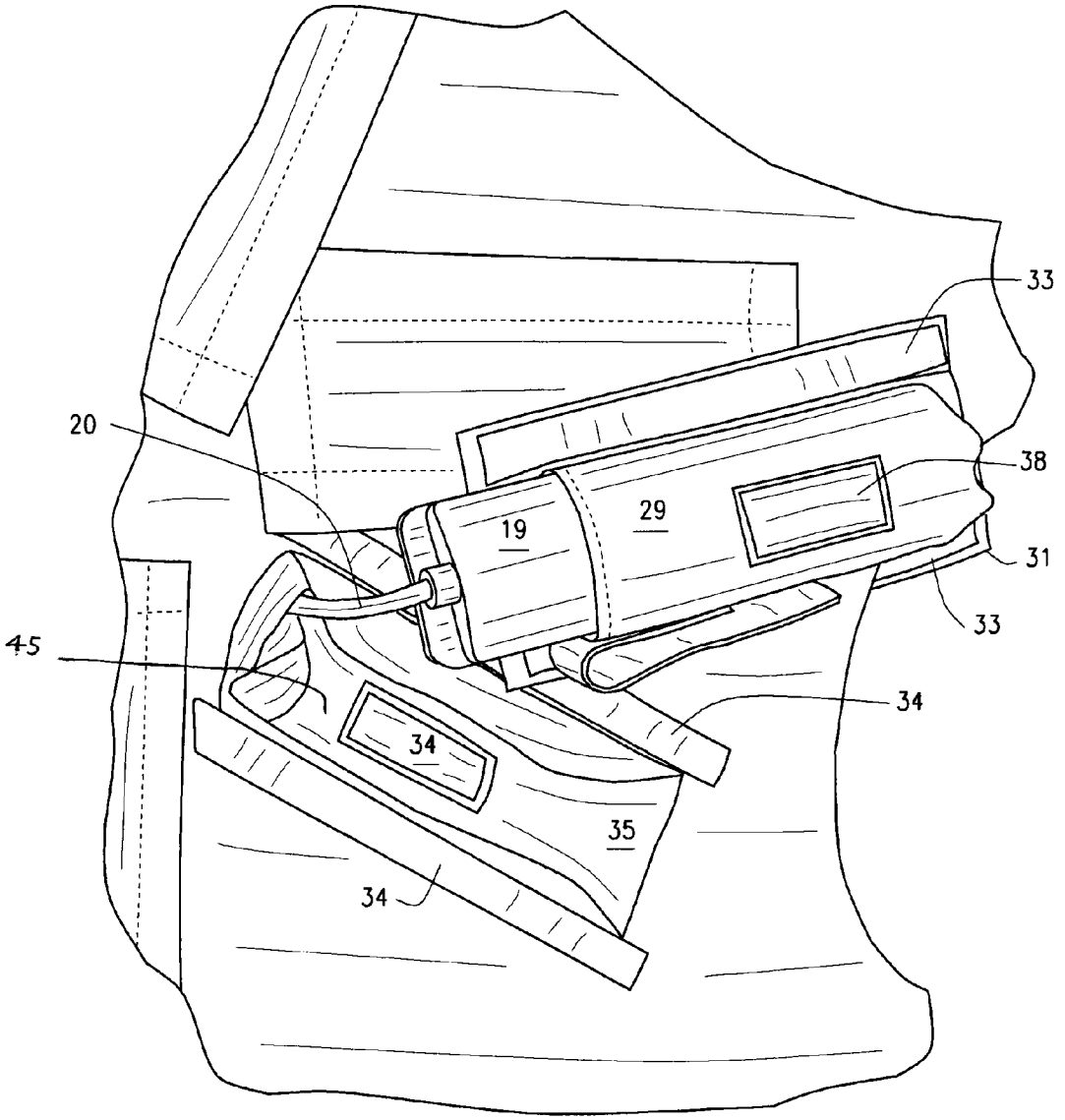


FIG. 8

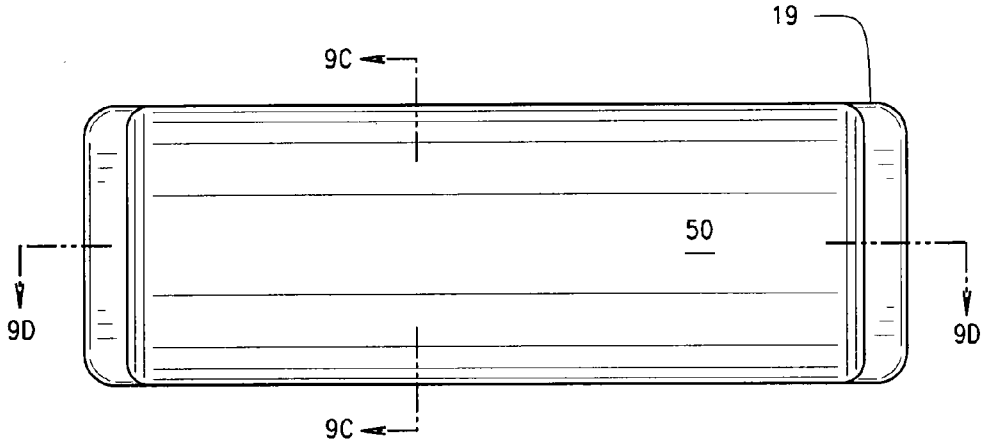


FIG. 9A

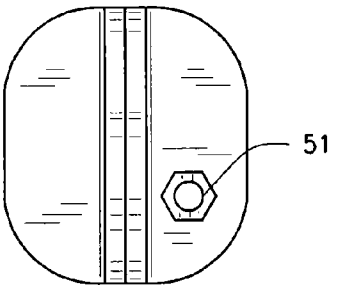


FIG. 9B

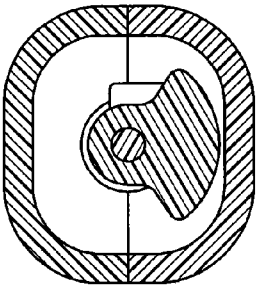


FIG. 9C

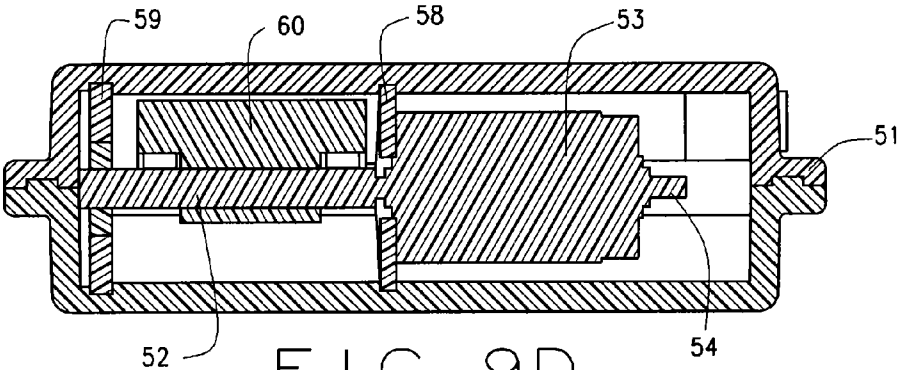


FIG. 9D

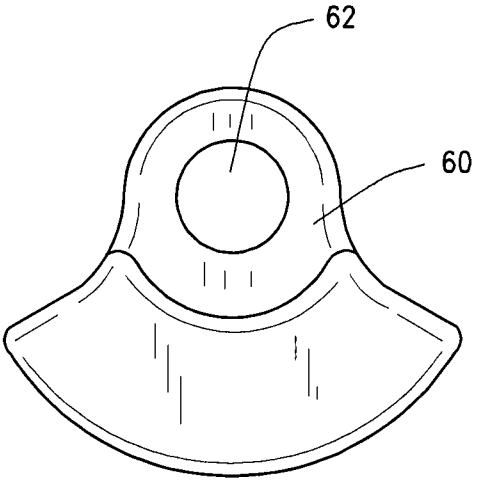


FIG. 10A

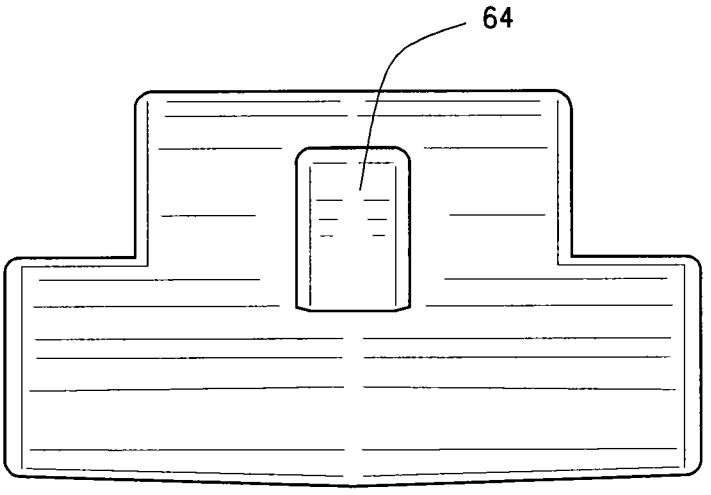


FIG. 10B

PORTABLE ARTICLE FOR ADMINISTERING THERAPY TO A USER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to provisional application 61/544,175 filed Oct. 6, 2011, which is incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] None

BACKGROUND OF THE INVENTION

[0003] This disclosure relates to a portable article including a device and method for administrating therapy to a user. While the disclosure is directed specifically to treating impaired airway clearance for users or patients suffering from a variety of medical conditions that the effect lung function of the patient, those skilled in the art will recognize the wider applicability of the inventive principles discussed hereinafter.

[0004] Medical conditions that would benefit from improved lung drainage and more effective airway clearance include Cystic Fibrosis, Bronchiectasis, Pneumonia, and all other COPD (Chronic Obstructive Pulmonary Disease), for example. Airway clearance is the elimination of excess mucus and contaminants from the lungs. Natural airway clearance is accomplished when certain body mechanisms interact effectively. Mucus is secreted to entrap harmful substances and keep airways clean; natural filters such as nasal hairs help capture contaminants; cilia continuously sweep mucus from the lower segments of the lungs to upper airways; and coughing and sneezing clears the mucus from the respiratory system.

[0005] Natural airway clearance is extremely important because the process helps people stay healthy and breather easier, Mucus that accumulate in the lungs may lead to very serious complications including death. Excessive or retained mucus creates an ideal environment for the growth of infection-causing pathogens. These infections can damage healthy lung tissue and make breathing more difficult.

[0006] The assignee of the present disclosure has had a long history in providing treatment for impaired airway clearance. Various commercial products were and are sold under its well-known trademarks, including merely by way of example and not of limitation, Flimm Fighter®, Directional-Stroking®, Neo-Cussor™ VibraCare®, Therassist®, and Medatilt. For years, patients with impaired airway clearance relied upon manual chest physical therapy (CPT). Products employing the Directional-Stroking® method are particularly effective for airway clearance. However, while these and other associated products work well for their intended purpose, they often are not easily adapted for self administration. That is to say, a second person (care giver) is needed for use with the product or products in conjunction with the therapy being applied to the patient. As indicated above, products employing the Directional-Stroking® technique are particularly effective in loosening and moving contaminants and mucus from the lungs, for example, to the larger airways (i.e. thorax), where they can be coughed out.

[0007] A series of products are known in the art which employ what their manufacturers refer to as high frequency chest wall oscillation techniques, most of which use a vest or wrap which is worn by the patient. An air compressor and at least one associated hose are connected from the air compressor to the vest or wrap. In operation, the air compressor must be continuously-connected to a 120 volt or 220 volt electrical power source throughout the full period of each treatment. While those products claim to be portable, all require an external bulky and noisy air compressor and connecting hose extending from the compressor to the vest or wrap, and an available connection to a 120 volt or 220 volt power source. The competitive systems are portable only in the analogous sense that the original portable compressors, weighing approximately fifteen pounds, were portable compressors. The vest and compressors can be lugged around, but they truly are not portable as that term has become to be understood in the art or by the consuming public.

[0008] As disclosed below, a completely safe, truly portable, self-contained, easy-to-use article is provided for unattended use by both children and adults. The article, sometimes referred to herein after as a G5® Freedom™ system, in one illustrative embodiment, includes a vest or wrap made operational by the provision of a plurality of recessed pockets and/or attachment provisions on or in the article positioned adjacent to the major lung segments, both topical and apical when the article is worn by the patient. The pockets or attachment provisions hold at least one self-contained power module or power pod adapted to provide the "Direction Stoking" forces to the patient without the need for an attendant or caregiver for the patient. As will be appreciated by those skilled in the art, the number of potential embodiments employing the inventive constructions disclosed hereinafter is limited only by one's imagination.

BRIEF SUMMARY OF THE INVENTION

[0009] In accordance with this disclosure, generally stated, a simplified, portable article is provided for administrating air way clearance therapy, for example, by the application of selective-segment, sequentially-synchronized percussive Directional Stroking force to the patient. In one preferred embodiment, the article includes a specialized vest which is worn by a patient during therapy. This vest has a plurality of pockets formed in it, each of which are sized to receive a power pod, placing the pods in close proximity to areas of the patient's body requiring therapy. The power pods are designed to provide therapy to the patient. An electronic controller enables the therapist or patient to select and control the manner in which each individual power pod is energized, and at what frequency, in which sequence, and at which specific location on the patient.

[0010] One feature of the disclosure is the ability to provide selective energy adjustment using a low voltage twelve volt power source, which even when combined with various forms of the article offers a low weight system when compared to other available therapeutic devices designed for similar purposes.

[0011] Another feature of the disclosure is the ability to provide an article which can be constructed to permit proper orientation of the power pods so as to apply the desired therapy at the specific location on a patient, for example, when using the article.

[0012] Another feature of the disclosure is the preferred construction of power pods for a particular article in which the enclosure of the power pods transmits the force to the patient

[0013] Yet another feature of the disclosure is that once the article is place on a patient, the treatment provides for hands free operation.

[0014] Another feature of the disclosure is the provision of a power pod construction which can be operated from a variety of power sources, including for example battery operation and/or air while the operation of any part of the article utilizing the power pod remains therapeutically consistent.

[0015] Other features of the disclosure will be apparent to those skilled in the art in view of the following description and accompanying drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0016] In the accompanying drawings which form part of the specification:

[0017] FIG. **1** is a diagrammatic view of one illustrative embodiment of article of the present disclosure;

[0018] FIG. **1**B is a diagrammatic view of a second illustrative embodiment, partly broken away, of the article show in FIG. **1**

[0019] FIG. **2** is a diagrammatic view showing the human lungs with which the embodiment of FIG. **1** finds application;

[0020] FIG. **3** is a diagrammatic view of the embodiment of FIG. **1** showing one illustrative arrangement of a connection diagram for a plurality of power pods employed with the embodiment of FIG. **1**.

[0021] FIG. **4** is a top plan view of one illustrative embodiment for control device shown in FIG: **1**.

[0022] FIG. **5**A-**5**D views of a second illustrative embodiment of article of the present disclosure;

[0023] FIG. **6** is a view in perspective, partly broken away, of the outward facing side of article shown in FIG. **1**;

[0024] FIG. **7** is a view in perspective of the inward patient facing side of the article shown in FIG. **1**;

[0025] FIG. **8** is an enlarged view in perspective, partly broken away taken about the line **8**-**8** in FIG. **7**, illustrating the power pod holder and one illustrative attachment method for the power pod;

[0026] FIG. **9**A is a top plan view of one illustrative embodiment of power pod employed with the embodiments of FIGS. **7** and **5**;

[0027] FIG. **9**B is an end view of the power pod shown in FIG. **9**A

[0028] FIG. **9**C is a sectional view taken along the line **9**C of FIG. **9**A

[0029] FIG. **9**D is a sectional view taken along the line **9**D of FIG. **9**A;

[0030] FIG. **10**A is an end view of an eccentric employed with the power pod of FIG. **9**; and

[0031] FIG. **10**B is a side view of the eccentric shown in FIG. **10**A.

[0032] Corresponding reference numerals indicate corresponding parts throughout the several figures of the drawings.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0033] The following detailed description illustrates the article for which Letters Patent is sought by way of example and not by way of limitation. This description will clearly enable one skilled in the art to make and use the invention, and describes several embodiments, adaptations, variations, alternatives and uses of the invention, including what I presently believe is the best mode of carrying out the invention.

[0034] Referring now to FIG. **1**, reference numeral **1** indicates one illustrative article of the present disclosure in one of its preferred forms. The embodiment of FIG. **1**, illustrates a device **3** in the form of a vest **22** worn by a user, as later described in greater detail. The vest **22** is operatively connected through a connector **5** to a control panel **7**. The control panel **7** has a first input side operatively connected to a controller **9** and a second input operably connected to a power source **15** through a suitable source of power, which in the embodiment is a low voltage power supply **11** and a connector **13**.

[0035] The power source **15** preferably is a source of 120-220 volt electrical energy commonly obtained at a conventional electrical plug connected to the power grid. The power supply **11** reduces the electrical energy from the power source **15** to a low level electrical source for the control panel **7**.

[0036] As will be appreciated by those skilled in the art, while FIG. **1** describes one source of electrical energy for operation of the device **1**, the power source **15** may be replaced by a battery source of energy **17** without altering other components of the device **1**. A battery power source is shown in FIG. **1**B. As can be further appreciated by those skilled in the art, while some form of electrical operation is preferred, the design also can be easily converted to accommodate an air powered source of energy in the form of a suitable air compressor. I have found, however, electrically energized forms of the article **1** are preferred in application use.

[0037] As is best seen in FIG. **7**, the article **1**, preferably in the vest **22** form, includes a first part **23** and a second part **24**. The vest **22** may assume a variety of configurations and designs. In the embodiment shown, the parts **23** and **24** are sized to cover the back and chest of the intended user and define a central head opening **25**. The parts **23** and **24** of the vest **22** are shown in diagrammatic form in FIG. **3**. As shown, the connector **5** is operatively associated with a circuit **20** which is arranged on or about the parts **23** and **24** so as to interconnect a plurality of power pods **19** carried by the parts **23** and **24**. The particular location of the power pods **19** with respect to the vest **22** is an important consideration. In the embodiment shown in FIG. **3**, for example, the power pod **19** locations are selected to overlay the lungs of a user on both of the chest and back sides of the user. Placement of the power pods **19** with respect to the lungs is illustratively shown in FIG. **2** and, as later described in greater detail, the power pods **19** operating to provide drainage of fluids from the lungs of a user so that the fluids can be naturally expelled by the user.

[0038] Referring now to FIG. **8**, the power pods **19** are mounted within a pocket **29** formed integrally with a cover part **31**. In the embodiment illustrated, the cover part **31** includes hook and loop fastening material **33** positioned along a longitudinal axis of the pocket part **29** and along the edges of the cover part **31**. Corresponding hook and loop material **34** is positioned about the mouth of a cavity **35** formed in the article **1**, and along a bottom wall **45** of the cavity **35**. The number of cavities required is a matter of design choice. In the preferred embodiment illustrated, four cavities **35** are formed in each of the parts **23** and **24** of the vest **22**. FIG. **8** illustrates the pocket **29** removed from a cavity **35**, while FIG. **7** shows a cover part **31** in position or in their respective cavities in the closed and operating position of the cover part **31**. Those skilled in the art will recognize that other

methods of attachment and placement of the power pods **19** are compatible the broader aspects of the disclosure.

[0039] FIG. **6** illustrates the vest **22** attached to a user of the device **1**. Preferably the vest **22** is worn by and attached to the user through the use of conventional strap **41** and snap buckles **38**. As shown in FIG. **6**, a pair of strap **41** and buckle **41** combinations function to attach the vest parts **23** and **24** of the vest **22** over the shoulders of the user. Similarly, the vest **22** also attaches to a user's torso in the embodiment shown in FIG. **6** and the parts **23** and **24** are maintained in position by an arrangement of strap **39** and buckle **38** combinations. Other methods of attachment will be apparent to those skilled in the art.

[0040] The buckles **38** and strap **41** combination along the top of the vest parts **23** and **24** , referenced to FIG. **6** act as shoulder straps and serve a practical function besides connecting the parts **23** and **24** of the vest **22**. I have found that use of the shoulder straps **41** allows the vest **22** to accommodate a variety of torso lengths for any particularly user, while the straps **39** and buckles **38** likewise can accommodate a variety of different physical configurations of the intended user so that one particular configuration of the vest **22** will accommodate users having a variety of physical body configurations. Those skilled in the art, of course, will recognize that the vest **22** may have a one piece construction if, desired.

[0041] One illustrative embodiment of the controller **9** compatible with the vest **22** is shown in FIG. **4**. As there shown, various operating configurations possible with article **1** of the present disclosure are shown in a general configuration. The controller **9** is intended to be programmable to offer a number of operational modes as later described in greater detail. Those skilled in the art will recognize that the controller **9** can assume a variety of design configurations and provide any number of operational modes for the vest **22**.

[0042] FIGS. **9** *a* through **9** *d* show one illustrative embodiment of the power pods **19** employed with the article **1**. Each of the power pods **19** includes a housing **50** preferably constructed in two parts. The housing **50** has a connection end **51** operatively connecting the power pods **19** to the circuit **20**. Each power pod **19** includes an electrical motor **53** having a connection **54** and an output shaft **52**. The shaft **52** is mounted for rotation within the housing **50** along bearing structures **58** and **59**. An eccentric **60** is mounted to the shaft **52** and rotates when the motor **53** is operated under the control of the controller **9**. Rotation of the eccentric **60** generates a directional stroking force through the housing **50** to the body of the intended user. As indicated herein, this is an important feature of the article **1** in general and the vest **22** in particular in that the power pods **19** themselves provide a therapeutic action for the vest **22** without outside assistance in the way or need for additional adapters, connectors or applicator devices generally require by the prior art. The eccentric **60** is specifically designed for mounting on the shaft **52** along an internal opening **62** through the use of conventional fasteners used to attach the eccentric **60** to the shaft **52** through an opening **64** in the body of the eccentric **60**.

[0043] While the power pods **19** find specific application in conjunction with the vest **22**, because of the unique design of the power pods, other physiotherapy applications are easily adaptable to their use. Merely by way of example, FIGS. **5** *a* through **5** *d* illustrate a therapeutic wrap **72** which may be placed on various extremities of a user for various therapy applications. As shown in FIG. **5** *b*, the wrap **72** has an application side **74** having a plurality of pockets **29** having a construction similar to the pockets **29** of the vest **22**. Preferably hook and loop fasteners permit wrap **72** attachment to areas requiring application therapy. Again, other connection or fastening methods are contemplated by this disclosure.

[0044] Operation of the article of this disclosure is relatively simple to understand. In the preferred embodiment, the multi-pocketed vest **22** incorporates eight power pods **19**, four at the lower lobe of each lung, one on each side of a patient's body; and, four at the upper lobe of each lung, one on each side of a patient's body, with each of the eight power pods **19** positioned so that the Directional Stroking® action of each of the power pods **19** is directed toward the patient's thorax. All eight of the power pods **19** are powered by an external 120 volt or 220 volt power source, reduced down to 12 or 24 volts, or can be individually powered by a single 12 volt or 9 volt battery pack which is maybe, for example carried in a pocket in the vest **22**, for complete portability (or, alternatively, each power pod **19** can be independently powered by a 9 volt or 24 volt battery attached to or within the body of vest **22**). The patient or therapist then activates the hand-held, electronic control module or controller **9** which sequentially-activates the four lower-lobe power pods **19**, all synchronized to provide Directional Stroking® percussion to the patient's lower lung lobes, at identical, slow frequencies of 20 cycles per second (CPS). After a pre-selected time (depending on the physical size of the patient), the controller **9** then automatically activates the remaining four upper-lobe power pods **19**, to provide Directional Stroking® percussion to the patient's two upper lobes, with all upper-lobe power pods **19** synchronized at a slightly-higher frequency of 30 CPS, to assist in mobilizing mucus toward the patient's thorax, where it can be coughed up. It should be noted that the higher vibratory frequency also stimulates the patient's cough mechanism in the patient's throat, thereby assisting in the elimination of damaging mucus and other fluids from the lungs of the patient.

[0045] Alternative uses of the selective-segmented, sequentially-synchronized operation of the vest **22** include uses for massage purposes and/or for lymphatic drainage, for example. By wrapping the vest **22** (or a special article **1**) around the leg of a patient, (See FIG. **5**) for deep-tissue massage, for sequentially-synchronized massage from a patient's lower leg, upward toward a patient's hip—or from a patient's lower back, upward toward a patient's shoulders.

[0046] Other programs for controller **9** operation will be apparent to those skilled in the art. In addition, while the controller **9** is shown as being hard wired to the control panel **7**, it is apparent that other forms of communication not requiring a physical connection are within the scope of the appended claims. Advances in both communication forms and electronic device advances may permit the elimination of the control panel completely, or may allow the distribution of the panel **7** functions directly to the power pod **19**. These variations are merely illustrative.

[0047] As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

[0048] In view of the above, it will be seen that the several objects and advantages of the present invention have been achieved and other advantageous results have been obtained.

1. An article for administrating therapy to a user, comprising:

a device worn by the user during therapy, the device including a first part and a second part, a plurality of pockets formed in the device and positioned adjacent to corresponding body surface areas of the user for the application of therapy;

a plurality of power pods for apply force to the user's body, the force applied by each power pod simultaneously applying a first force component perpendicular to the user's body surface and a second force component parallel to the user's body surface;

an electrical circuit carried by the device for connecting each of said power pods to an electrical input connection;

a control panel having at least two input sides and an output side, the output side being operably connected to the electrical input connection of the electrical circuit;

a power supply operably connected to one of said at least two input sides of said control panel; and

a user controller operatively connected to the other of said at least two input sides of said control panel.

2. The article of claim **1** wherein the control panel is integrally formed with one of the first and second parts of said device.

3. The article of claim **1** wherein the controller is hardwired to the control panel.

4. The article of claim **1** wherein the power supply is hardwired to the control panel.

5. The article of claim **1** wherein the power supply comprises at least one battery.

6. The article of claim **1** wherein the first and second parts of said device are attached to one another by a pair of shoulder straps.

7. The article of claim **6** wherein the shoulder straps are adjustable.

8. The article of claim **1** further includes at least one adjustable closure between the first and second parts of the device for attaching the article to the user.

9. The article of claim **1** wherein the controller includes a plurality of programs for operating the power pods in a plurality of selectable modes of operations.

10. The article of claim **1** wherein the article is a vest worn by the user and the power pods are arranged to loosen and liquefy fluids along and mobilize the liquids for the trachea of the user.

11. The article of claim **10** where in the article is portable.

12. A portable article for administrative therapy to a user comprising:

a device worn by the user during therapy, the device having at least one area corresponding to the user body surface for which therapy is desired;

at least one power pod for apply force to the user's body attachable to the device corresponding to said at least one area, the force applied by the at least one power pod simultaneously applying a first force component perpendicular to the user's body surface and a second force component parallel to the user's body surface; and

a power supply operatively connected to said at least one power pod.

13. The article of claim **12** further including a control panel operatively connected between the power supply and the at least one power pod.

14. The article of claim **13** where in the control panel is integrally formed with the device.

15. The article of claim **14** further including a controller operatively associated with the control panel.

16. The article of claim **15** wherein the power supply is hardwired to the control panel.

17. The article of claim **12** wherein the power supply comprises at least one battery.

18. The article of claim **12** wherein the device includes a first part and a second part, a plurality of pockets formed in the device and positioned adjacent to corresponding body surface areas of the user for the application of therapy, and the first and second parts of said device are attached to one another by a pair of shoulder straps.

19. The article of claim **18** wherein the shoulder straps are adjustable.

20. The article of claim **19** further includes at least one adjustable closure between the first and second parts of the device for attaching the article to the user.

21. The article of claim **20** wherein the controller includes a plurality of programs for operating the at least one power pod in a plurality of selectable modes of operation.

22. The article of claim **21** wherein the article is a vest worn by the user, further including a plurality of power pods, wherein the power pods are arranged to loosen and liquefy fluids along and mobilize the liquids for the trachea of the user.

23. The article of claim **22** wherein the power pods further include a housing, an electric motor having a shaft driven by the motor, and an eccentric mounted for rotational movement to the shaft within the housing such that operation of the motor and shaft causes the housing to apply a first force component perpendicular to the user's body surface and a second force component parallel to the users body surface.

24. An article for administering therapy to a user, comprising:

a device attachable to the user having at least one area corresponding to a user body surface for which therapy is desired;

at least one power pod associated with the device for applying force to the user's body surface where therapy is desired;

an electrical circuit associated with the device for operatively connecting at least on power pod to a source of electrical energy;

a control panel having at least two input sides and an output side, the output side being operably connected to the electrical circuit of the device;

a power supply operably connected to one of said at least two input sides of said control panel; and

a user controller operatively connected to the other of said at least two input sides of said control panel.

25. The article of claim **24** wherein the power supply is at least one battery.

26. The article of claim **24** wherein the device includes a first part and a second part, and a plurality of pockets formed in the device and positioned adjacent to corresponding body surface areas of the user for the application of therapy

27. The article of claim **26** wherein the first and second parts of said device are attached to one another by a pair of shoulder straps.

28. The article of claim **27** wherein the shoulder straps are adjustable.

29. The article of claim **28** wherein the article is a vest worn by the user and the power pods are arranged to loosen and liquefy fluids along and mobilize the liquids for the trachea of the user.

30. A portable article for administering therapy to a user comprising:

a device attachable to the user having at least one area corresponding to a user body surface for which therapy is desired;

at least one power pod associated with the device for apply force to the user's body surface corresponding to said at least one area, the force applied by at least one power pod simultaneously applying a first force component perpendicular to the user's body surface and a second force component parallel to the user's body surface; and

a power supply operatively connected to said at least one power pod.

31. The portable article of claim **30** wherein the power pod includes housing, and the force applied by the power pod is applied through the housing to the user's body surface.

32. The portable article of claim **31** wherein the power pod further includes an electric motor having a shaft driven by the motor, and an eccentric mounted for rotational movement to the shaft such that operation of the motor and shaft causes the housing to apply the first force component perpendicular to the user's body surface and a second force component parallel to the users body surface.

* * * * *

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(12) **United States Patent**
Ignagni et al.

(10) **Patent No.: US 7,927,293 B1**
(45) **Date of Patent: Apr. 19, 2011**

(54) **MEANS FOR CLEARING MUCUS FROM THE PULMONARY SYSTEM**

(76) Inventors: **Mario Ignagni**, Brooklyn Park, MN (US); **Thomas J. O'Dea**, Shoreview, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 952 days.

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A61H 7/00 (2006.01)
A61H 19/00 (2006.01)

(52) **U.S. Cl.** **601/46**; 601/150; 601/151

(58) **Field of Classification Search** 601/41–44, 601/46, 48, 71, 148–152
See application file for complete search history.

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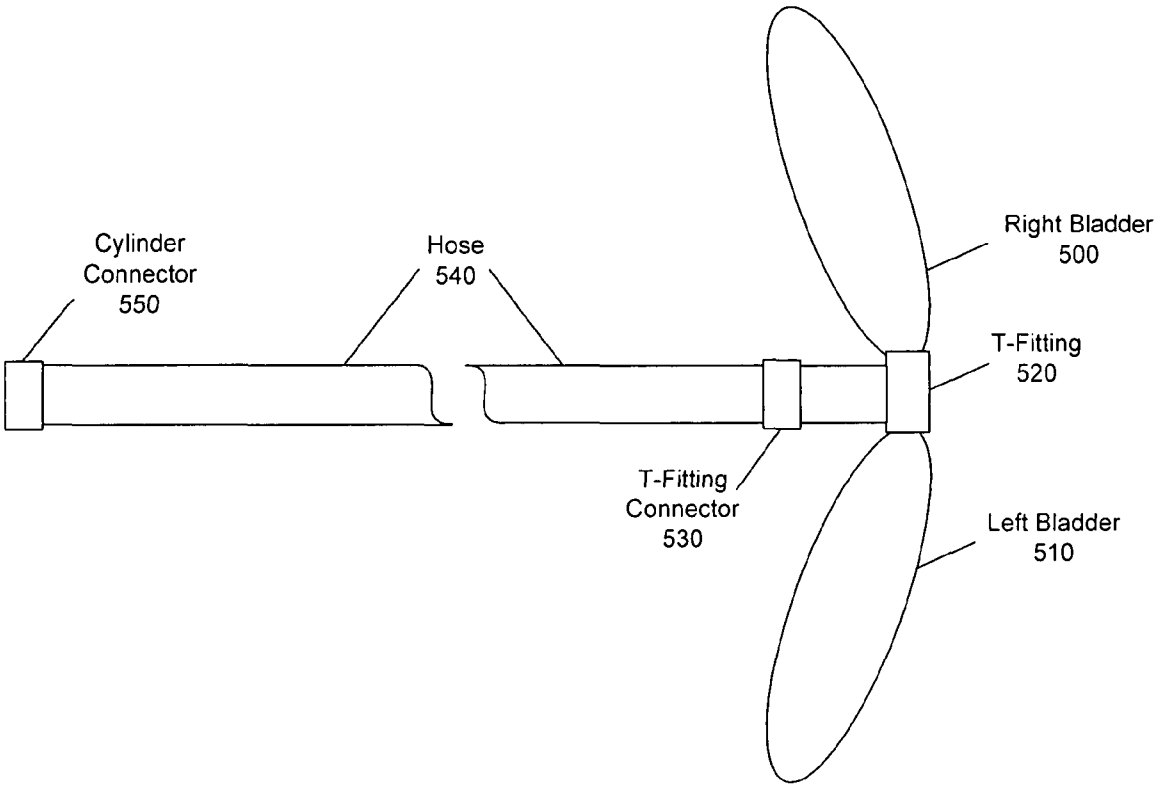
Primary Examiner — Kristen C Matter

(57) **ABSTRACT**

An apparatus for clearing mucus from the pulmonary system, utilizing two different types of external excitation applied concurrently to the thorax, the first type of excitation consisting of vibrational stimulations, and the second type of excitation consisting of compressive stimulations, with control means provided to regulate the two excitation means.

10 Claims, 4 Drawing Sheets



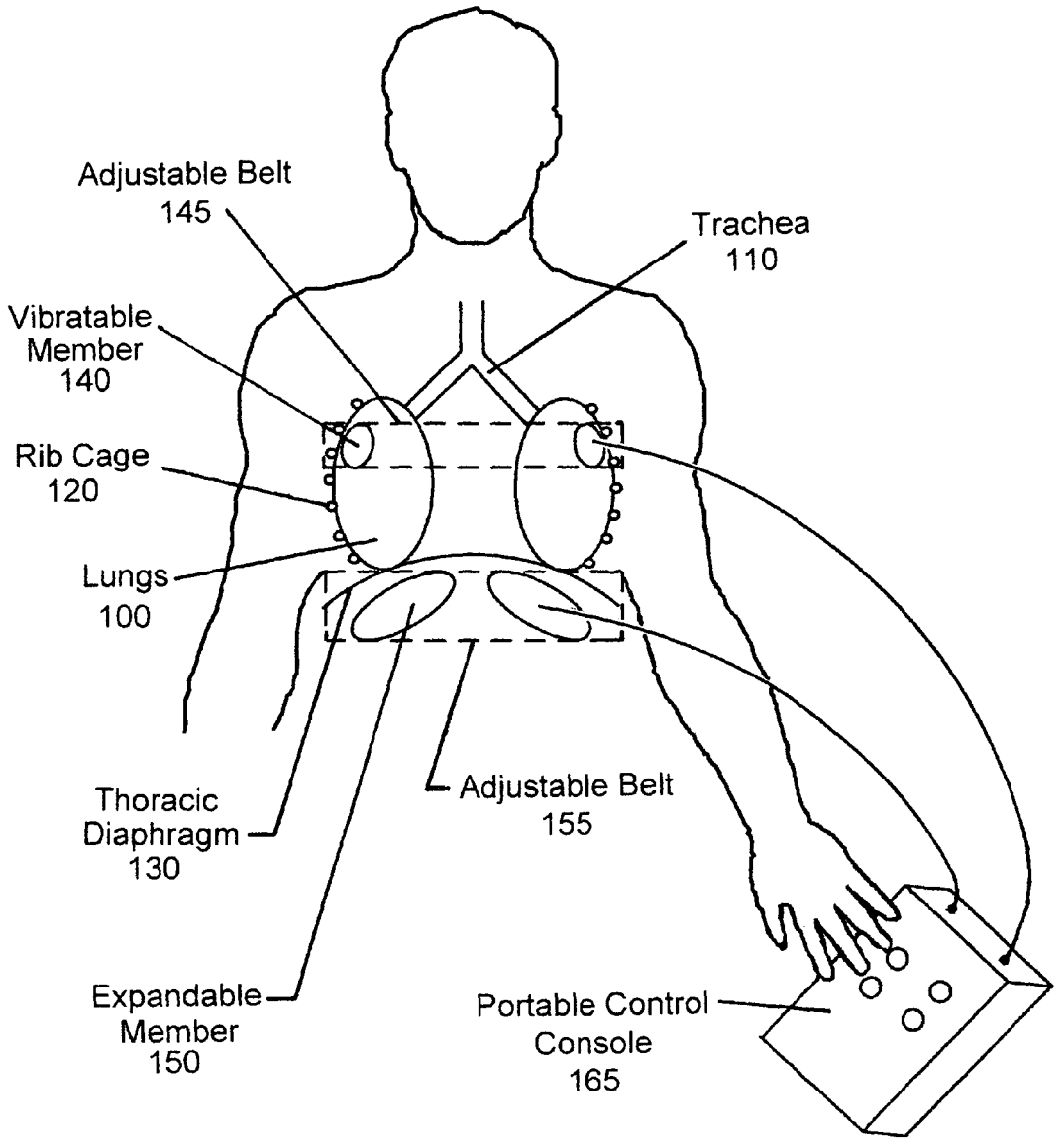

Adjustable Belt
145
Trachea
110
Vibratable
Member
140
Rib Cage
120
Lungs
100
Thoracic
Diaphragm
130
Adjustable Belt
155
Expandable
Member
150
Portable Control
Console
165

Fig. 1

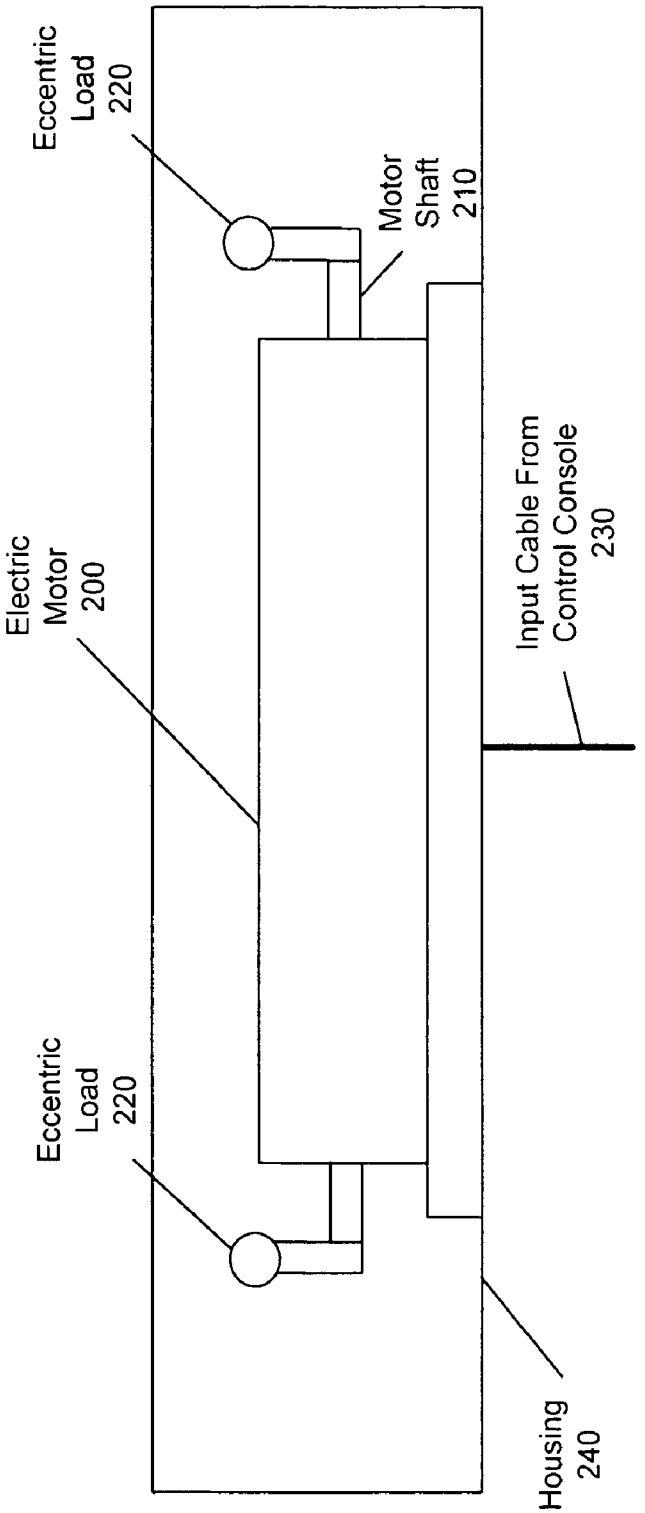

Eccentric Load 220
Motor Shaft 210
Input Cable From Control Console 230
Electric Motor 200
Eccentric Load 220
Housing 240

Fig. 2

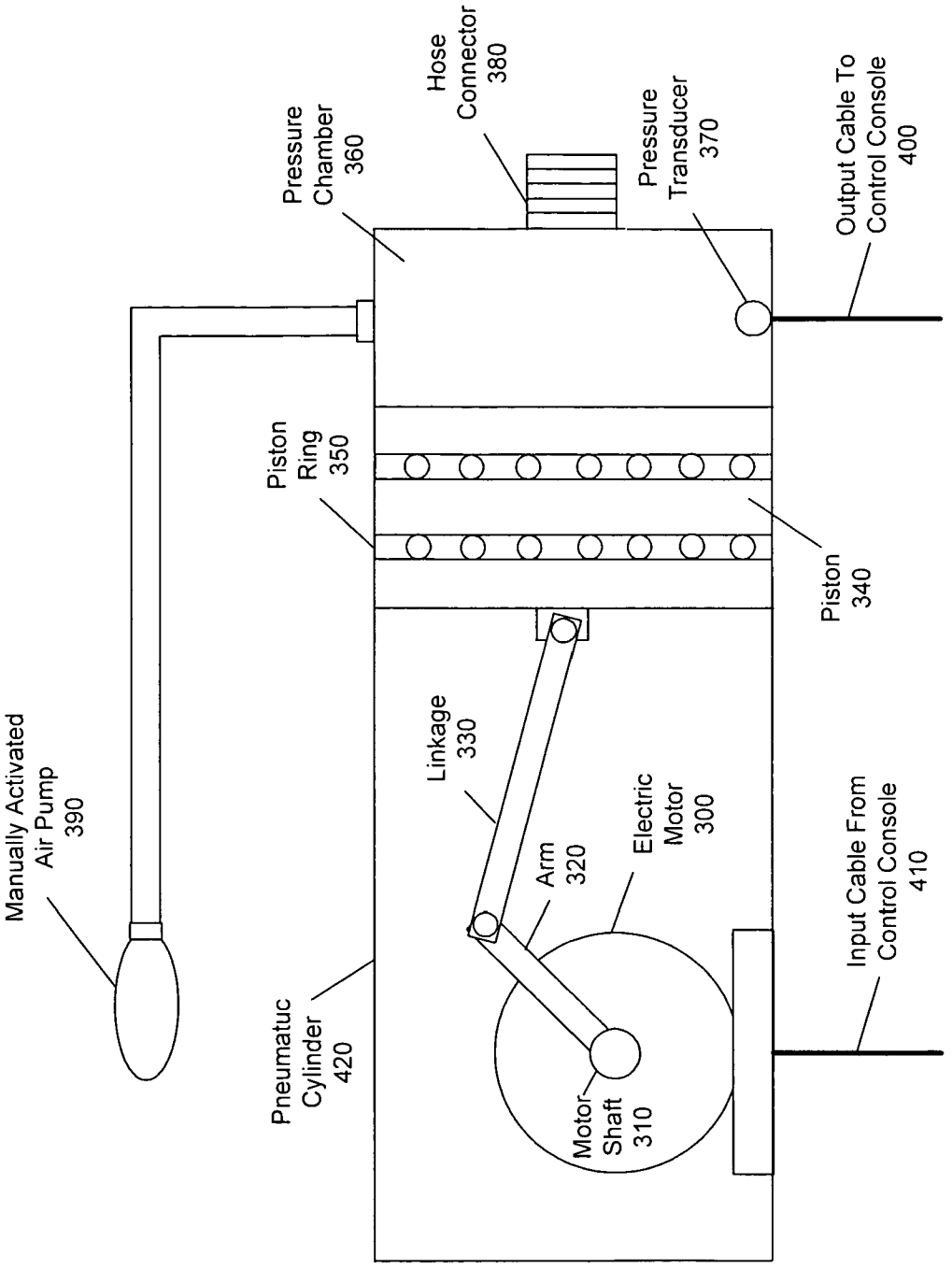

Pressure Chamber 360
Hose Connector 380
Pressure Transducer 370
Output Cable To Control Console 400
Piston Ring 350
Piston 340
Linkage 330
Arm 320
Electric Motor 300
Input Cable From Control Console 410
Manually Activated Air Pump 390
Pneumatuc Cylinder 420
Motor Shaft 310

Fig. 3

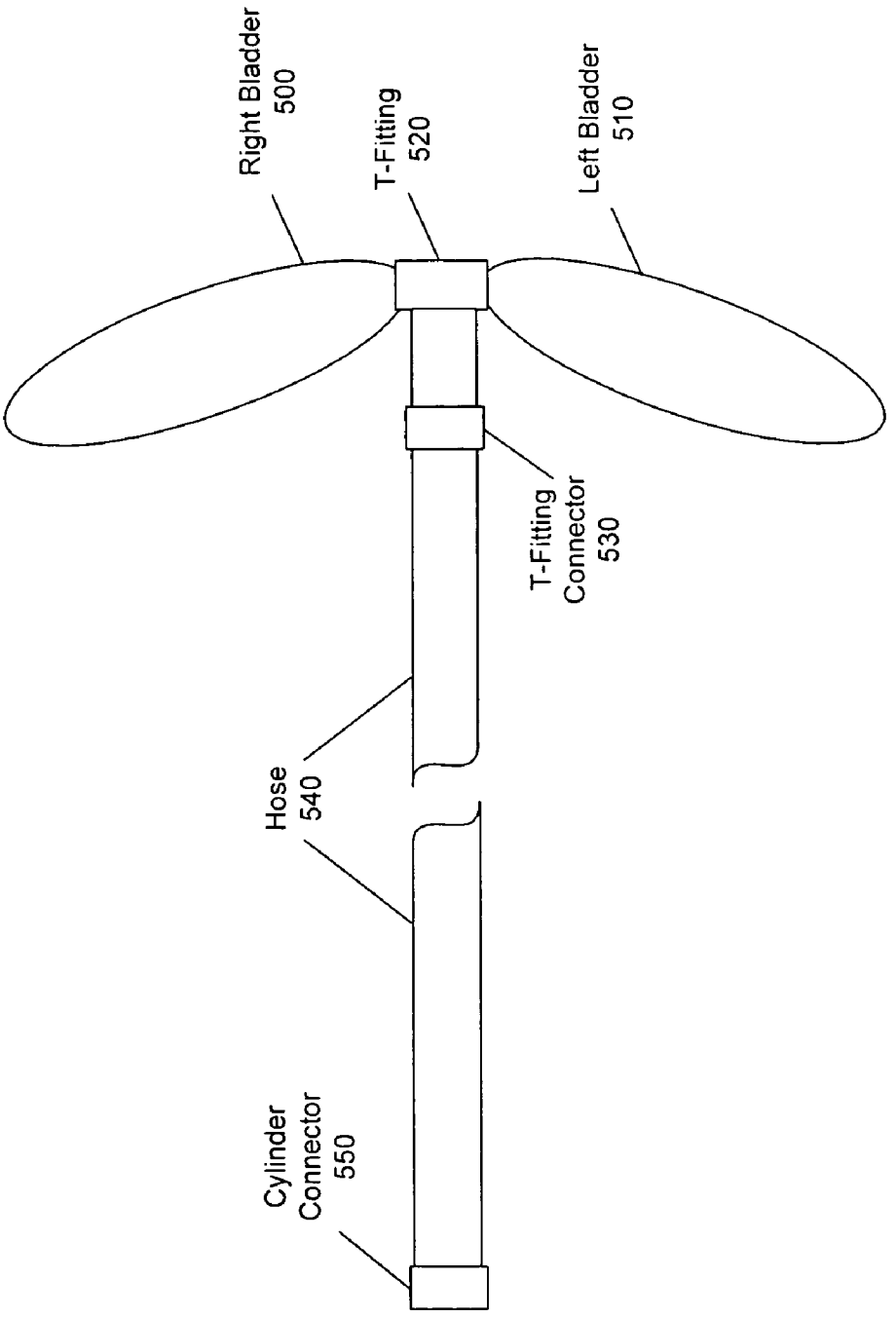

Right Bladder
500
T-Fitting
520
Left Bladder
510
T-Fitting
Connector
530
Hose
540
Cylinder
Connector
550

Fig. 4

MEANS FOR CLEARING MUCUS FROM THE PULMONARY SYSTEM

FIELD OF THE INVENTION

The invention generally relates to the use of mechanical stimulation of the thorax to promote clearance of mucus from the lungs and trachea.

BACKGROUND OF THE INVENTION

A number of diseases can lead to severe impairment of normal lung functioning. Among these are: Cystic Fibrosis, Emphysema, and Immotile Celia Syndrome. Cystic Fibrosis is a hereditary disease that leads to the accumulation of large quantities of viscous mucus in the lungs. Emphysema causes impairment of the lung's ability to clear mucus as a result of damage to the celia, the small hair-like vibrating appendages covering the lung wall that loosen and help propel the mucus out of the lung; and damage to the alveoli, the small air sacs covering the lung surface, which are instrumental in coughing mucus out of the lungs. Immotile Celia Syndrome is a hereditary disease in which the normal functioning of the celia is absent or impaired, leading to the accumulation of mucus in the lungs. In all of these diseases, mucus retained in the lungs becomes a natural breeding ground for harmful bacteria that can cause repeated bouts of serious infections, as well as leading to decreased respiratory gas exchange.

In addition to drugs and inhalants, various physical therapies may be applied to assist in expelling mucus from the pulmonary system. In particular, patients may undergo chest percussion by a trained physical therapist to loosen lung mucus, which is followed by postural drainage and coughing to expel the mucus from the lungs. This can be a time consuming and discomforting therapy which meets with only limited success, especially if the patient is in a weakened condition.

More recently, high-frequency chest compression techniques have been employed as a means of eliminating the need for a physical therapist, and to improve effectiveness of mucus clearance from the lungs. Such techniques have been taught by Warwick and Hansen, U.S. Pat. No. 4,838,263; Hansen, U.S. Pat. No. 5,569,170; and Warwick and Hansen, U.S. Pat. No. 6,958,046. High-frequency chest compression, as applied by an inflatable vest, has been shown in clinical trials and in actual use to be efficacious in clearing mucus from the lungs. However, a patient may require 2 to 3 hours of treatment each day to keep the lungs relatively free of mucus.

The present invention addresses the need for a more effective approach to clearing mucus from the pulmonary system that will reduce physical stress to the body, and require less time in the daily regimen of treatment.

BRIEF SUMMARY OF THE INVENTION

A first source of excitation applies vibrational stimulations directly to the thorax which, in turn, causes the pulmonary system to develop small-amplitude sympathetic vibrations, thereby loosening the mucus attached to the lungs and trachea. A second independent source of excitation applies compressive stimulations to the patient just below the rib cage, leading to upward thrusts of the thoracic diaphragm. Since the lungs rest directly on the thoracic diaphragm, localized motions of the lung walls will be initiated at the points of contact. This causes the air in the lungs to experience pressure and flow-rate pulsations which, in turn, cause the mucus attached to the lungs and trachea to be propelled in incremental steps toward the mouth. Control means are provided to insure that efficacious pulmonary system vibration and thoracic compressions are achieved without undue stress to the patient. The use of two separately controllable thoracic excitation sources offers greater potential for optimization than a single excitation, as applied by existing high-frequency chest compression techniques, and may have advantages in size, cost, mucus clearance rate, and reduced physical stress to the body.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates the parts of the body which are affected by the external excitations, and the primary elements used in generating the excitations.

FIG. **2** illustrates an exemplary embodiment for transmitting vibrational stimulations to the thorax.

FIG. **3** illustrates an exemplary embodiment for producing pneumatic pressure variations.

FIG. **4** illustrates an exemplary embodiment for transmitting pressure stimulations to the thorax.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** illustrates the concept for clearing the lungs (**100**) and trachea (**110**) of mucus. The concept is based on the employment of two separately controllable excitations, in combination, to maximize the effectiveness of mucus clearance from the pulmonary system. The first excitation augments the action of the cilia by inducing sustained low-amplitude high-frequency vibrations in the lungs (**100**). This serves to create continuous oscillatory translational motions of the lung wall relative to the mucus which, in turn, expedites movement of the mucus. Vibration of the lung walls is achieved by employing at least one vibratable member (**140**) held in contact with the thorax. From a physical perspective, the lung wall behaves essentially like a perfect elastic membrane, while the mucus does not. Accordingly, because the lung wall and mucus respond differently in a vibrational environment, relative motion will occur between them, which creates a boundary layer of lower viscosity mucus adjacent to the lung wall, thereby increasing mucus mobility.

Given that sustained vibration of the lung wall expedites the movement of mucus, the second function of propelling the mucus along the lung wall is achieved by mechanically pumping the air in the lungs (**100**) utilizing compressive stimulations of the lower thorax, characterized by a much higher amplitude and lower frequency than the vibrational stimulations. Compression of the lower thorax is achieved by employing at least one expandable member (**150**) held in contact with the thorax, which leads to upward thrusts of the thoracic diaphragm (**130**). The pressure and flow-rate variations of the air enclosed within the lungs (**100**), induced by the upward thrusts of the thoracic diaphragm (**130**), create the motive forces required to propel the mucus in incremental steps toward the mouth, where it can be swallowed or expectorated.

The first excitation means for applying vibrational stimulations to the thorax can take various forms. In one exemplary application, the vibrational stimulations could be applied by one or more well-known mechanical vibrators which transmit inertial reaction forces to the thorax. In still another exemplary application, the vibrational stimulations could be applied by sonic waves originating from one or more audio speakers. In yet another exemplary application, the vibrational stimulations could be applied by an inflatable pneumatic belt or cuff that causes oscillatory compressive forces to

be transmitted to the thorax. More than one vibration-generating device would typically be utilized, with vibration applied symmetrically to the thorax, allowing the lungs (**100**) and the trachea (**110**) to be stimulated. In one exemplary application, the vibration-generating devices would be held in contact with the thorax by an adjustable belt (**145**). In still another exemplary application, the vibration-generating devices would be attached to the back or side of a chair, and the thorax positioned such that direct contact is maintained with the vibration generators.

Since each patient generally responds differently to external vibrational stimuli, control means are required to regulate these stimulations, such that the vibrations transmitted to the pulmonary system are effective in increasing the mobility of the mucus attached to the lungs (**100**) and trachea (**110**) without causing undue stress to the patient. This will depend both on the degree of mucus congestion, and on the mechanical properties of the lungs (**100**) and rib cage (**120**). For example, the lung resonant frequency of a small child will be approximately twice that of an adult. Furthermore, the lung resonant frequency will generally be significantly different when the lungs (**100**) are congested with mucus. A second physical difference between patients is the rib-cage resonant frequency, which has an important influence on the efficacy of the vibrational stimulations. Since the lungs (**100**) can be vibrated both directly, and indirectly as a response to vibration of the rib cage (**120**), mucus loosening will benefit from both types of excitation. Also, generally, for a given spectral content of the vibrational energy transmitted to the thorax, efficacy of mucus clearance from the lungs (**100**) and trachea (**110**) will depend directly on the intensity of the vibrations, which should be subject to regulation by the patient or caregiver to achieve the desired benefit without undue stress.

Regulation of the vibrational stimulations is achieved by employing a portable control console (**165**)operated by the patient or caregiver. This would generally include the ability to regulate the vibration spectrum applied to the thorax, as well as the intensity of the vibrations in a well-known manner. It is also important that the patient or caregiver be given the means to terminate the vibrational excitations, both as a safety measure, and to allow the patient time to rest or cough. Application of vibration during the inspiration phase of the breathing cycle may also be undesirable for some patients, and could be discontinued during this part of the respiratory cycle.

A general set of specifications placed on the control console (**165**) that allows regulation of the vibrational excitations is defined by:

- a power cable input for conveying standard AC power from a wall outlet;
- an AC to DC converter;
- a microprocessor for implementing control means for regulating the vibrational stimulations;
- software algorithms embedded in the microprocessor for generating commands to the vibration generators;
- digital to analog converter for generating an analog voltage command to the vibration generators;
- an amplifier for adjusting the amplitude of the analog voltage command to the vibration generators;
- one or more control knobs allowing adjustment of the spectral content of the vibrational stimulations;
- a control knob allowing adjustment of the intensity of the vibrational stimulations; and
- a dormancy button which terminates application of the vibrational stimulations upon release.

The control console (**165**) serves as the energizing source for the vibrations generators using well-known means in the art. It performs this function by receiving standard AC power from a wall outlet via an input power cable. However, because the vibration generators would typically utilize a DC input, an AC to DC converter would need to be provided. To allow a control signal responsive to a broad range of patient needs to be synthesized, a microprocessor for generating the control signal input to the vibration generators would be required. Applicable software algorithms for generating digitized commands to the vibration generators would be embedded in the microprocessor. An analog voltage input to each vibration generator, provided by a digital to analog converter, would be passed through an amplifier to allow the voltage level to be adjusted as required.

FIG. **2** illustrates an exemplary embodiment for creating vibrational excitations to the thorax. Vibration is achieved in this exemplary application by employing a small electrical motor (**200**), with eccentric load (**220**), to create inertial reaction forces. The electric motor (**200**) could be a servo motor responsive to a continuous command input, or a stepper motor responsive to a high-frequency stream of discrete incremental positioning commands. To minimize the creation of undesirable rotary vibrations, the electric motor (**200**) would have both ends of a single motor shaft (**210**) accessible for mounting identical eccentric weights, and be mounted such that the center of gravity of the combination of electric motor (**200**), motor shaft (**210**), and eccentric load (**220**) is coincident with the center of gravity of the housing (**240**). An input cable (**230**) provides voltage commands to the electric motor (**200**), allowing its speed to be controlled in a desired manner, with the opposite end of the cable being connected to the control console.

In the exemplary embodiment of FIG. **2**, the perpendicular force transmitted to the thorax is defined by

$$F = \frac{2Wr\omega^2}{g}\sin\omega t \tag{1}$$

where

F=perpendicular force applied to thorax

W=weight of each eccentric mass

g=acceleration due to gravity

ω=angular velocity of motor shaft

r=radial distance from motor spin axis to center of mass of eccentric load

t=time

It is seen that the perpendicular force defined by (1) varies sinusoidally and, for a constant spin rate of the electric motor (**200**), has a constant peak amplitude. More generally, if the spin rate of the electric motor (**200**) varies cyclically about a constant mean value, addition sinusoidal components at frequencies both higher and lower than the basic spin frequency will be generated. The weight of the eccentric load (**220**) used in the vibrator should be periodically re-evaluated to insure compatibility with a particular patient's needs. As a patient ages, and grows in size and weight, his physical response to the vibrations will change, and this should be reflected in the weights used.

The application of vibration to the pulmonary system causes a significant increase in the mobility of the mucus attached to the lungs (**100**) and trachea (**110**); however, in itself, the vibration has little potential for expelling mucus from the pulmonary system. To accomplish the latter, a second type of excitation is required which applies compressive stimulations to the lower thorax, inducing a series of huffs. Application of compressive stimulations to the lower-tho-

racic region can be achieved by various well-known means. In one exemplary application, an electromechanical actuator would be used to apply compressive forces directly to the thorax. In still another exemplary application, the compressive stimulations would be transmitted by means of one or more inflatable bladders held against the thorax by an adjustable belt (**155**), and pressurized by a controlled source of pneumatic pressure. In yet another exemplary application, the compressive stimulations would be transmitted by means of a single inflatable cuff or belt, secured around the lower thorax, and pressurized by a controllable source of pneumatic pressure

As in the case of the vibrational stimulations, the compressive stimulations need to be controlled to reflect patient-specific requirements, and to achieve overall efficacy without discomfort to the patient. The objective of the control scheme is to regulate the compressions of the lower-thoracic region in a well-known manner which creates simultaneous increases in the pressure and expiration rate of air contained within the lungs (**100**) and trachea (**110**), thereby leading to a series of huffs. Then, together with concurrent application of the vibrational stimulations, the compressive stimulations will cause the desired incremental movements of the mucus along the lung and tracheal walls. Generally, compressive stimulations would be applied only during the expiration phase of the respiratory cycle, and inhibited by the patient or caregiver during the inspiration phase.

The control console (**165**) provides the means by which the patient or caregiver may regulate the compressive stimulations to the lower thorax in a well-known manner. To accomplish this, additional control console features are required, as follows:

- software algorithms embedded in the microprocessor for generating commands to the actuator producing the compressive stimulations;
- a digital to analog converter for generating an analog voltage input to the actuator;
- an amplifier for adjusting the amplitude of the analog voltage input to the actuator;
- an electrical cable for transmitting the electrical voltage to the actuator;
- a control knob allowing adjustment of the frequency of the compressive stimulations;
- a control knob allowing adjustment of the amplitude of the compressive stimulations; and
- a dormancy button which terminates application of the compressive stimulations upon release.

The control console (**165**) serves as the energizing source for the actuator producing the compressive stimulations. It performs this function by utilizing the available standard AC power. However, because the actuator would typically utilize a DC input, an AC to DC converter would be required. A microprocessor for implementing the control signal input to the actuator would also be provided. Applicable software algorithms for generating digitized commands to the actuator would be embedded in the microprocessor. An analog voltage input to the actuator would be provided by a digital to analog converter and this, in turn, would be adjusted by an amplifier before being passed on to the actuator.

FIG. **3** depicts an exemplary embodiment for creating compressive stimulations to the lower-thoracic region. In this exemplary embodiment the compressive stimulations are provided by a pneumatic cylinder (**420**) which applies compressions by means of at least one expandable member (**150**) held in contact with the lower-thoracic region by a belt (**155**). To insure efficacy and safety, control means are provided to regulate the compressive stimulations applied to the thorax. This would normally take the form of a well-known amplitude control allowing adjustment of the amplitude of the compressive stimulations transmitted to the lower-thoracic region, and a well-known frequency control allowing adjustment of the frequency of the compressive stimulations.

In the exemplary embodiment illustrated in FIG. **3**, an electric motor (**300**) is employed for converting an electrical control signal input into a translational motion of a piston (**340**) contained within a pneumatic cylinder (**420**). Piston rings (**350**) allow the piston (**340**) to operate with a minimum of friction, and also provide a seal between the compartment of the pneumatic cylinder (**420**) housing the electric motor (**300**), and the pressure chamber (**360**). The electric motor (**300**) creates a rotary motion of the motor shaft (**310**) and arm (**320**) which, in turn, causes translational motion of the piston (**340**) via motion of the linkage (**330**). The translational motion of the piston (**340**), in turn, causes pressure buildup in the pressure chamber (**360**), which leads to pressure variation in the air flow from the pneumatic cylinder (**420**). The electric motor (**300**) receives a control signal that positions the motor shaft (**310**) via an electrical input cable (**410**), which has its opposite end connected to the control console. A pressure transducer (**370**) generates an electrical signal responsive to the pressure of the air in the pressure chamber (**360**) of the pneumatic cylinder (**420**). In addition, an electrical output cable (**400**) for transmitting the voltage from the pressure transducer (**370**) to the control console is provided. FIG. **3** also shows an optional manually-activated air pump (**390**) for creating a desired quiescent pressure in the pressure chamber (**360**) when the piston (**340**) is in its null position. The manually activated air pump (**390**) could be used as an alternative to positioning the piston (**340**) as the means of creating a desired quiescent pressure in the pressure chamber (**360**). A desired value of the quiescent pressure can be conveniently set using the output of the pressure transducer (**370**).

The embedded software hosted in the microprocessor controls the pressure variations transmitted to each expandable member (**150**) in a well-known manner such that the desired lung pressure/flow-rate response is produced. The control is intended to produce a series of huffs, each of which causes a buildup of pressure and flow rate of air within the lungs (**100**) that serves to propel the mucus in incremental steps out of the lungs (**100**) and trachea (**110**). The objective is to produce compressions that build up and terminate smoothly, such that the patient experiences minimal discomfort. Normally, a number of individual compressions would be applied during the expiration phase, the goal being approximately two to three if possible. However, when a great deal of lung congestion exists, the patient may experience very shallow breathing, in which case only a single compression of the lower-thoracic region may initially be possible during expiration. The availability of the pressure transducer (**370**) allows closed-loop control of the electric motor (**300**), such that a desired pressure variation can be transmitted to each expandable member (**150**). The control algorithms would be hosted in the microprocessor, and operate on the difference between the pressure measured by the pressure transducer (**370**) and a desired pressure profile. A digital realization of the pressure measured by the pressure transducer (**370**) would be obtained by employing an analog to digital converter located in the control console.

FIG. **4** illustrates an exemplary embodiment for applying compressive stimulations to the lower-thoracic region. A plurality of at least one inflatable bladder held in contact with the lower-thoracic region receives the pressurized air flow from the pneumatic cylinder (**420**) via a hose (**540**) connected to the pneumatic cylinder (**420**) by means of a hose connector

(380). In this exemplary embodiment, two symmetrically disposed inflatable bladders, the right bladder (500) and the left bladder (510), are used to provide compressive stimulations to the abdominal wall and thoracic diaphragm (130). The use of two bladders held symmetrically against the lower thorax allows compressive forces to be transmitted to both lungs (100) via the abdominal wall and thoracic diaphragm (130). A single hose (540) connected to the pneumatic cylinder (420) conveys the compressed air to the right bladder (500) and left bladder (510) via a T-fitting (520). The hose (540) is connected to the pneumatic cylinder (420) by means of a cylinder connector (550), and to the T-fitting by means of a T-fitting connector (530). The right bladder (500) and left bladder (510) can be held firmly against the lower-thoracic region by means of a non-extensible belt, as is well known in the art, which causes the compressive forces to be directed inwardly against the lower-thoracic region as is well known in the art.

The embodiments described herein are sufficiently detailed to allow those skilled in the arts to practice the claimed invention, and it is understood that other embodiments may be utilized without departing from the true spirit of the claimed invention.

What is claimed is:

1. An apparatus for clearing mucus from the pulmonary system of a human, comprised of:

means for applying first external stimulations to the thorax of said human, whereby said first stimulations are low-amplitude, high-frequency stimulations adapted to cause vibrations to be transmitted to the pulmonary system comprised of the lungs and trachea of said human;

first control means to regulate said first external stimulations, whereby said vibrations transmitted to said pulmonary system are adapted to cause the mobility of mucus attached to said lungs and trachea to be increased;

means for applying second different external stimulations to said thorax, whereby said second different stimulations are high-amplitude, low-frequency stimulations adapted to cause compressions of the lower-thoracic region comprised of the abdominal wall and thoracic diaphragm of said human;

second control means to regulate said second different external stimulations, whereby said compressions of said lower-thoracic region are adapted to cause induced expiration responses in said pulmonary system, whereby simultaneous increases in the pressure and expulsion rate of air contained within said lungs and trachea occur in use; and

a control console activated by the patient or caregiver, whereby desired levels and temporal variations of said first external stimulations and said second different external stimulations are applied to said thorax in use;

whereby concurrent application of said first external stimulations and said second different external stimulations to said thorax is adapted to cause movement of said mucus from said lungs and trachea.

2. The apparatus of claim 1, wherein said means for applying said first external stimulations to said thorax is further comprised of:

at least one vibratable member adapted to be held in contact with said thorax by an adjustable restraining device, whereby said first external stimulations are transmitted to said thorax in use.

3. The apparatus of claim 2, further comprised of:

a first electromechanical actuator for converting an electrical voltage into an oscillatory motion of an inertial mass; and

a housing for containing said first electromechanical actuator and said inertial mass, said housing is adapted to be held against said thorax by said adjustable restraining device, whereby inertial reaction forces are transmitted to said thorax in use.

4. The apparatus of claim 3, further comprised of:

a power cable input for conveying standard AC power from a wall outlet;

an AC-to-DC converter;

a microprocessor for implementing said first control means;

a set of software algorithms embedded in said microprocessor for generating digital commands to said first electromechanical actuator;

a digital-to-analog converter for generating an analog voltage input to said first electromechanical actuator from said digital commands;

an amplifier for adjusting the amplitude of said analog voltage input to said first electromechanical actuator; and

an electrical cable providing said analog voltage to said first electromechanical actuator, said electrical cable having its opposite end connected to said amplifier.

5. The apparatus of claim 1, wherein said control console is further comprised of:

a frequency control allowing adjustment of the frequency of said first external stimulations;

an amplitude control allowing adjustment of the amplitude of said first external stimulations; and

a dormancy button which terminates application of said first external stimulations upon release.

6. The apparatus of claim 1, wherein said means for applying said second different external stimulations to said thorax is further comprised of:

at least one expandable member adapted to be held in contact with said thorax by an adjustable restraining device, whereby said second different external stimulations are transmitted to said lower-thoracic region in use.

7. The apparatus of claim 6, further comprised of:

a second electromechanical actuator for converting an electrical control signal input into a translational motion of a piston contained within a pneumatic cylinder, whereby said translational motion of said piston causes pressure variations in air flow from said pneumatic cylinder;

at least one inflatable bladder is adapted to be held in contact with said lower-thoracic region for receiving said air flow from said pneumatic cylinder;

a hose for connecting said pneumatic cylinder to said at least one inflatable bladder, whereby said pressure variations are transmitted to said at least one inflatable bladder;

an optional manually activated air pump for creating a desired quiescent pressure in said pneumatic cylinder; and

a pressure transducer responsive to the pressure in said pneumatic cylinder.

8. The apparatus of claim 7, further comprised of:

a microprocessor for implementing said second control means;

a set of software algorithms embedded in said microprocessor for generating translational commands to said second electromechanical actuator for positioning said piston within said pneumatic cylinder;

a digital-to-analog converter for generating an analog voltage input to said second electromechanical actuator for positioning said piston within said pneumatic cylinder;

an analog-to-digital converter for generating a digital realization of the voltage output of said pressure transducer;

an amplifier for adjusting the amplitude of said analog voltage input to said second electromechanical actuator for positioning said piston within said pneumatic cylinder;

an electrical cable for transmitting said analog voltage input to said second electromechanical actuator for positioning said piston within said pneumatic cylinder, said electrical cable having its opposite end connected to said amplifier; and

an electrical cable for transmitting an electrical voltage output from said pressure transducer to said microprocessor.

9. The apparatus of claim **8**, further comprised of:

a software module for generating a feedback control signal to said second electromechanical actuator for positioning said piston, said feedback control signal being proportional to the difference between a desired pressure variation profile and the actual pressure variation profile measured by said pressure transducer.

10. The apparatus of claim **1**, wherein said control console is further comprised of:

a control allowing adjustment of the amplitude of said second different external stimulations;

a control allowing adjustment of the frequency of said second different external stimulations; and

a dormancy button which terminates application of said second different external stimulations upon release.

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