



(51) International Patent Classification:

<i>A63B 23/18</i> (2006.01)	<i>A63B 21/00</i> (2006.01)
<i>A61B 5/08</i> (2006.01)	<i>A63B 23/00</i> (2006.01)
<i>A61M 16/20</i> (2006.01)	

(21) International Application Number:

PCT/US2019/018024

(22) International Filing Date:

14 February 2019 (14.02.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/710,395 16 February 2018 (16.02.2018) US

(71) **Applicant:** UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC. [US/US]; University of Louisville, Office of Technology Transfer, 300 East Market Street, Suite 300, Louisville, Kentucky 40202 (US).

(72) **Inventors: ROUSSEL, Thomas, J.:** 419 Lutz Hall, Belknap Campus, University of Louisville, Louisville, Kentucky 40245 (US). **HARKEMA, Susan, J.:** 220 Abraham Flexner Way, Louisville, Kentucky 40202 (US). **OVECHKIN, Alexander, V.:** 220 Abraham Flexner Way, Suite 1520, Louisville, Kentucky 40202 (US). **CHEN, Yangshen:** 220 Abraham Flexner Way, Suite 1520, Louisville, Kentucky 40202 (US). **TRAN, Kevin:** 10708 Taylor Farm Court, Prospect, Kentucky 40059 (US). **BROWN JR., Edward, Hoyt:** 504 Hillside Lane, Louisville, Kentucky 40207 (US).

(74) **Agent: BRIDGES, Max E.** et al.; Wyatt, Tarrant & Combs, LLP, 500 West Jefferson Street, Suite 2800, Louisville, Kentucky 40202 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,

(54) Title: RESPIRATORY TRAINING AND AIRWAY PRESSURE MONITORING DEVICE

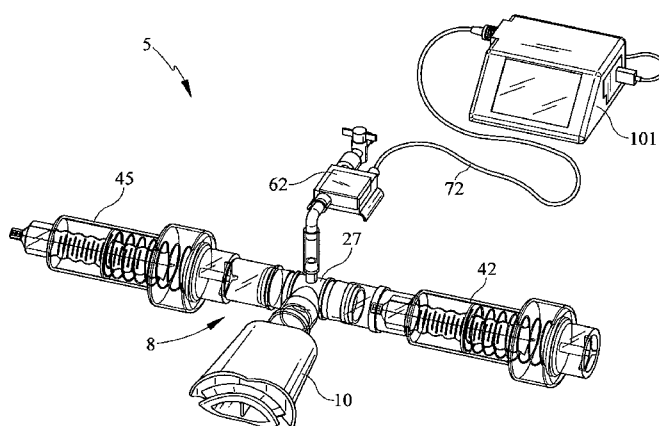


Figure 1

(S7) Abstract: A respiratory training device providing both inspiratory and expiratory functional evaluation and training, as well as independent regulation of both the inspiratory and expiratory airway resistance levels used during training. The respiratory training device also includes data acquisition, recording, storage, retrieval and display functions for airway pressure monitoring data to provide functional evaluation, physiological monitoring, and diagnostic features. The respiratory training device allows the user to easily develop and follow precise and advanced training protocols, and utilize the respiratory device in both the clinical and home setting.

MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

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

UNITED STATES PATENT AND TRADEMARK OFFICE AS RECEIVING OFFICE
PCT NONPROVISIONAL PATENT APPLICATION

RESPIRATORY TRAINING AND AIRWAY PRESSURE MONITORING DEVICE

CROSS REFERENCE TO RELATED U.S. APPLICATION

[0001] This international nonprovisional patent application claims priority to and benefit from U.S. Provisional Patent Application Serial No. 62/710,395, titled “Respiratory Training and Airway Pressure Monitoring Device,” filed on 16 February 2018, which is hereby incorporated by reference in its entirety.

FIELD OF INVENTION

[0002] The embodiments described herein relate to respiratory training and testing devices, sometimes referred to as respiratory devices, which are for functional evaluation, training and quantifying a user’s respiratory and cardiovascular fitness and for those wanting or needing to improve their respiratory-cardiovascular performance. The respiratory devices of the present embodiments provide respiratory function measurements, reciprocal inspiratory and expiratory training, as well as independent regulation of both the inspiratory and expiratory resistance levels to be set during training sessions. Further embodiments provide for data acquisition, recording, storage, retrieval and display functions for airway pressure monitoring data to provide functional evaluation, visible feedback for users, progress monitoring, and diagnostic features.

BACKGROUND

[0003] A number of underlying physical conditions exist in which pulmonary and cardiovascular dysfunction are manifest in an individual. An abbreviated list of such conditions include spinal cord injury, neurological disorders, chronic obstructive pulmonary

disease (COPD), cardiopulmonary and/or cardiovascular disease, stroke, and sleep apnea. In the United States, pulmonary and cardiovascular dysfunction is consistently reported as a leading cause of morbidity and mortality among over 1.2 million people with chronic effects of spinal cord injury. By 2020, it is projected that these types of pulmonary and cardiovascular dysfunctions will be ranked first in terms of the burden of disease created by these conditions.

[0004] In this regard, “expiratory” refers to breathing out, or exhaling, and “inspiratory” refers to breathing in, or inhaling. Currently, respiratory muscle training devices and techniques using either inspiratory *or* expiratory trainers have been used in a rehabilitative approach to improve pulmonary function in some patients with respiratory, pulmonary, and/or cardiovascular deficits or who suffer from the aforementioned chronic diseases. Current respiratory muscle training devices and techniques have also been used to provide respiratory training for athletes to improve respiratory performance and cardiovascular function, for professionals who need to improve vocal function (such as singers, actors), or for any individual that desires to improve their respiratory capacity. Herein, the terms “user” and “patient” are used interchangeably to describe an individual that desires to improve their respiratory capacity.

[0005] In therapy or training sessions, users challenge their lungs and keep the muscles that control the lungs active to prevent atrophy, to increase total lung capacity, to increase peak oxygen consumption, or some combination of these and other desired results. In short, it is known that respiratory muscle training/therapy efforts can enhance breathing performance and improve health.

[0006] However, a number of conventional respiratory training devices are typically directed to either inspiratory training *or* expiratory training, but not both. However, if a user desires to train for both inspiration and expiration breathing, they must remove their

mouthpiece and switch the mode in between therapy devices for inhalation and exhalation or change devices completely (for devices that are only one way). But in doing so, an inefficiency is created because inspiration and expiration are inextricably linked. In many patients, it is not just a problem of insufficient airflow to the lungs, but also of insufficient ventilation, such that two separate conditioning devices would then be needed for an adequate training program that exercises both inspiratory and expiratory breathing. *See e.g.* Gea, J. et al., Respiratory diseases and muscle dysfunction. *Expert Rev Respir Med.* 2012 Feb;6(1):75-90. doi: 10.1586/ers.11.81; Ovechkin, A. et al., Respiratory motor training and neuromuscular plasticity in patients with chronic obstructive pulmonary disease: A pilot study. *Respir Physiol Neurobiol.* 2016;229:59-64. doi: 10.1016/j.resp.2016.04.003. PubMed PMID: 27137413; PMCID: PMC4887410.

[0007] Conventional respiratory training devices present a number of other disadvantages, such as the inability to independently regulate the resistance level of both inspiration and expiration. This shortcoming presents a particular problem to users that desire to develop and implement a training regimen. If users cannot independently regulate the resistance level of both the expiratory and inspiratory levels, then they cannot establish threshold training values and cannot adjust these levels as their training progresses making it much more difficult to improve their respiratory strength. Accordingly, conventional respiratory training devices fail to offer a good balance of functional evaluation, progress monitoring, diagnostic features for training purposes, nor do they develop precise and advanced training patterns for users.

[0008] Typically, the conventional respiratory training device consists of either small, personal devices or multi-featured training devices designed for the clinical setting. However, regardless of the setting, these conventional respiratory training devices present a number of other disadvantages. For example, the typical hand-held, personal devices that may be taken home by a user focus only on training and are designed to specifically target

and activate respiratory muscles. Typically, these conventional personal devices can only provide measurement of a user's expiratory capacity during one steady deep exhale. For user feedback during an exhalation, users typically see a ball or indicator rise and fall during a full exhale. However, these conventional devices do not show the full capacity of the lungs, are limited to solely expiratory measurements, and fail to quantify inspiratory capacities. Furthermore, the measurements during exhalation are often recorded manually. As a result, these conventional portable devices are typically rudimentary, provide limited functionality, and provide limited accuracy for the user.

[0009] In clinical settings, the conventional respiratory training devices are more advanced and provide more features, but these conventional devices are quite bulky, expensive (i.e. ranging in price from \$800 to \$32,000), and lack many important features such as the independent regulation of the inspiration and expiration resistance levels. In addition, these clinics may be a long distance from the patient and there may be significant gaps between visits to the clinic which make it difficult to implement a training regimen. Due to their size and significant price, these bulky clinical devices are simply not suitable for a user that desires to improve their respiratory performance away from the clinic environment.

[0010] In respiratory devices, it is often desirable to utilize a valve in which to control the air flow. However, the commercial electronic proportional valves often utilize small flow paths (e.g. 1/8 of an inch diameter) that can only function in environments with high pressure (such as 100 pounds per square inch ("psi")) and high flow rates. Thus, the conventional electronic proportional valves are not suitable for use in a respiratory training device because they create too much resistance, particularly for a user with compromised pulmonary function.

[0011] Accordingly, there is a significant need for a respiratory training device that provides both expiratory and inspiratory muscle training with adjustable independent

regulation of inspiration and expiration. Such an improvement would eliminate the need for two separate breathing devices and would facilitate the development and implementation of training regimens. Likewise, there is a need to continuously monitor and record airway pressure monitoring data during training to provide for evaluation, progress monitoring, provide diagnostic features, and develop advanced training sessions. There is a significant need for closed loop control of the training device's adjustable valves to separately regulate the inspiration and expiration threshold levels. Such a feature would allow the user and/or physician to develop and implement advanced training regimens. There is also a need for a portable and affordable device that may be used in both a clinical and home setting. Along with other features and advantages outlined herein, respiratory training devices within the scope of present embodiments meet these and other needs. In doing so, the respiratory training devices within the scope of present embodiments develop advanced training regimens for users, inform users about their training progress over time, and operate in low pressure and low flow rate environments.

SUMMARY OF EMBODIMENTS

[0012] Respiratory training devices according to multiple embodiments and alternatives provide both inspiratory and expiratory muscle training, as well as independent regulation of both the inspiratory and expiratory airway resistance levels. The respiratory training device also includes data acquisition, recording, storage, retrieval and display functions for airway pressure monitoring data to provide functional evaluation, progress monitoring, and diagnostic features. An exemplary (i.e., non-limiting) respiratory training device in accordance with present embodiments also provides features that allow the user to develop precise and advanced training protocols, and utilize the respiratory device in both the clinical and home setting.

[0013] Current embodiments provide for a respiratory training device that comprises a bi-directional breathing apparatus (i.e. both inspiratory and expiratory), a pressure sensor, and a processing unit configured to record, store, retrieve and display the airway pressure monitoring data and to control the various functions of the training device. In some embodiments, the processing unit is connected to a touchscreen display to generate training programs based on functional measurements, to guide the user through the various training sessions, display the results of the training, and provide visual output from the therapy session to the user. In other embodiments, the breathing apparatus, pressure sensor, and processing unit are a standalone device that is battery-powered or plugged into an outlet, with communication capabilities that wirelessly connect to remote device such as a mobile phone or tablet with an app. The instant (or scheduled) transmission of the respiratory data to a display or mobile app allows a clinician to provide feedback and encouragement to the patient, and allows the clinician to adjust the user's training program as needed. In addition, the transmission of the respiratory training data informs the physician of the patient's progress and motivates the patient to comply with their training regimen when performed outside of the clinic.

[0014] In some embodiments, the bi-directional breathing apparatus consists of a mouthpiece that can be flanged and disposable, a connector with two one-way valves, a pressure port to expose the pressure to a pressure sensor, an inspiratory trainer device, and an expiratory training tube. In some embodiments, the one-way valves in the connector open and close with each other such that air can only go through the inspiratory trainer device or out the expiratory training tube, but not both. In other words, when the user inhales, air passes only through the one-way valves of the inspiratory trainer device, through the connector, and through the mouthpiece. When the user exhales through the mouthpiece, the one-way valves in the connector block air from going through the inspiratory trainer device,

and instead the air travels through the other one-way valves of the connector and out the expiratory training tube. Current embodiments also provide for manual independent airway resistance adjustment in both the inspiratory trainer and the expiratory training tubes. In some embodiments, the user adjusts the air resistance by manual manipulation of compression springs inside the airway valves. In other embodiments, the processing unit includes a valve controller that electromechanically controls an adjustable valve and the user manually adjusts the valve controller by manually entering the desired airway resistance level into the processing unit. Accordingly, these embodiments provide for both expiratory and inspiratory muscle training with adjustable independent regulation of inspiration and expiration. These embodiments allow a clinician or user to develop precise and advanced training sessions.

[0015] In some embodiments, a pressure sensor is connected to the pressure port of the connector. During operation, the pressure sensor detects and measures the air pressure generated when the user both inhales and exhales through the bi-directional breathing apparatus. As previously noted, in some embodiments the pressure sensor is connected to a processing unit, and in other embodiments the sensor is wirelessly connected to a remote device. Regardless, the respiratory training device according to present embodiments includes a data recording function to save and display the airway pressure monitoring data generated during the training session. Furthermore, in some embodiments the processing unit or the remote device (utilizing a mobile app in a non-limiting example) can guide the user through a training session, to display prompts guiding a user through a training session, receive user input, display live air pressure data during a training session, and display the results such that the user can monitor their progress. Accordingly, these embodiments provide for functional evaluation and progress monitoring of the user's training, and provide diagnostic features for training purposes.

[0016] In some embodiments, the specific parts that are used in manufacturing a respiratory training device can be obtained as “off the shelf,” disposable, sterilized and biocompatible components. In addition, the respiratory training device in current embodiments is small and lightweight. These embodiments ensure that the respiratory training device is affordable, can be easily repaired using interchangeable parts, may be utilized by the user at home or in a clinical setting, and satisfies the United States Pharmacopoeia Class VI requirements established to safeguard the quality of health care technologies. Furthermore, current embodiments provide for a respiratory training device with a large flow path (e.g. 1 inch diameter) that is suitable for the lower pressure training situations that typically arise in therapy sessions.

BRIEF DESCRIPTION OF THE FIGURES

[0017] The drawings and embodiments described herein are illustrative of multiple alternative structures, aspects, and features of the present embodiments, and they are not to be understood as limiting the scope of present embodiments. It will be further understood that the drawing figures described and provided herein are not to scale, and that the embodiments are not limited to the precise arrangements and instrumentalities shown.

[0018] Fig. 1 is a perspective view of a respiratory training device, according to multiple embodiments and alternatives.

[0019] Fig. 2 is a perspective view illustrating the air flow paths through a respiratory training, according to multiple embodiments and alternatives.

[0020] Fig. 3 is an exploded view of a respiratory training device, according to multiple embodiments and alternatives.

[0021] Fig. 4 is a perspective view of a hollow tube that could be used as either an inspiratory or expiratory trainer device, according to multiple embodiments and alternatives.

[0022] Fig. 5 is a cross-sectional view along line V-V in Fig. 4 of an inspiratory or expiratory trainer device, according to multiple embodiments and alternatives.

[0023] Fig. 6 is an exploded view of a connector for a respiratory training device, according to multiple embodiments and alternatives.

[0024] Fig. 7 is a perspective view of a user interface and processing unit, according to multiple embodiments and alternatives.

[0025] Fig. 8 is a partial view of a connector and a perspective view of a pressure sensor and a processing unit, according to multiple embodiments and alternatives.

[0026] Fig. 9 is a plan view of an attachment for determining the maximum inhale and maximum exhale pressure of a user, according to multiple embodiments and alternatives.

[0027] Fig. 10 is a block diagram illustrating a control device system for data acquisition, recording, storage, retrieval and display functions, according to multiple embodiments and alternatives.

[0028] Fig. 11 is a block diagram illustrating a control device system for data acquisition, recording, storage, retrieval and display functions wherein a respiratory training device communicates wirelessly with a remote controller, according to multiple embodiments and alternatives.

[0029] Fig. 12A-12C is a flow chart illustrating the operation processes of a respiratory training device, according to multiple embodiments and alternatives.

[0030] Fig. 13 shows a portion of the user interface display of a respiratory training device, according to multiple embodiments and alternatives.

[0031] Fig. 14 shows a portion of the user interface display of a respiratory training device, according to multiple embodiments and alternatives.

[0032] Fig. 15 shows a portion of the user interface display of a respiratory training device, according to multiple embodiments and alternatives.

[0033] Fig. 16 shows a portion of the user interface display of a respiratory training device, according to multiple embodiments and alternatives.

[0034] Fig. 17 shows a portion of the user interface display of a respiratory training device, according to multiple embodiments and alternatives.

[0035] Fig. 18 shows a portion of the user interface display of a respiratory training device, according to multiple embodiments and alternatives.

[0036] Fig. 19 shows a portion of the user interface display of a respiratory training device, according to multiple embodiments and alternatives.

[0037] Fig. 20 shows a portion of the user interface display of a respiratory training device, according to multiple embodiments and alternatives.

[0038] Fig. 21 provides example results of a user training session with a respiratory training device, according to multiple embodiments and alternatives.

MULTIPLE EMBODIMENTS AND ALTERNATIVES

[0039] In some embodiments, a respiratory training device (sometimes referred to herein as a respiratory device for training a user's respiratory fitness), comprises a bi-directional

airflow assembly **8**. In some embodiments, the bi-directional airflow assembly **8** comprises an inspiratory training tube **42**, an expiratory training tube **45**, a connector **27**, and a mouthpiece **10**, each having a hollow portion. As desired, these parts for the bi-directional airflow assembly **8** are detachable. In some embodiments, the connector is joined directly to the other three parts listed above or, alternatively, joiner is established by adapters that preserve one or more flow paths described herein and defined by the hollow portions of these parts.

[0040] In some embodiments, each of the inspiratory training tube **42** and expiratory training tube **45** comprises a valve **60** that lets air flow into the tube when a user inhales through the mouthpiece, or valve **60** lets air flow out of the tube when a user exhales into the mouthpiece. Accordingly, the inspiratory training tube, connector, and mouthpiece define one flow path for air drawn into the bi-directional airflow assembly **8**, while the expiratory training tube, connector, and mouthpiece define a different, second flow path for air blown out of the bi-directional airflow assembly **8**. Further, a respiratory training device **5** according to multiple embodiments and alternatives comprises a pressure sensor **62** in communication with a first volume of the bi-directional airflow assembly **8** representing a first flow path and a second volume representing a second flow path, in order to obtain an air pressure data within such volumes of the bi-directional airflow assembly **8**. Said air pressure data will generally be associated with the user inhaling through, or exhaling into, the mouthpiece during use of device **5**. In some embodiments, the air pressure data consists of the inhale pressure, the exhale pressure, the date, the time, and the length of the training session.

[0041] Fig. 1 shows respiratory training device **5** according to multiple embodiments and alternatives. Respiratory training device **5** includes mouthpiece **10**, connector **27**, inspiratory

training tube **42**, expiratory training tube **45** and pressure sensor **62**. In some embodiments, connector **27** is a tee connector. In some embodiments, respiratory training device **5** is connected to a processing unit **101** by a pressure sensor wire **72**. In other embodiments, the respiratory training device **5** is a stand-alone unit powered by a battery or plugged into an outlet and wirelessly connected to a remote device (e.g. a phone, tablet, or other device). As a non-limiting example, a stand-alone respiratory training device **5** could be connected to a separate device via Bluetooth® technology.

[0042] In Fig. 2, the arrows **82** illustrate the air flow path when a user inhales through the respiratory training device **5**, referred to herein as a first flow path, and arrows **85** illustrate the air flow path when a user exhales, referred to herein as a second flow path. In some embodiments, connector **27** includes one-way valve **30** and one-way valve **31**, wherein one-way valve **30** is located near the inspiratory training tube port **38**, and one-way valve **31** is near the expiratory training tube port **35**. In some embodiments, one-way valve **30** and one-way valve **31** in the connector **27** open and close with each other such that air can only go through the inspiratory trainer device **42** or out the expiratory training tube **45**, but not both. In other words, when the user inhales through the respiratory training device **5**, air passes along the path shown by arrows **82** through the inspiratory training tube **42**, through the connector **27**, and through the mouthpiece **10**. When the user exhales through the mouthpiece **10**, one-way valve **30** and one-way valve **31** in the connector **27** block air from going through the inspiratory training tube **42**, and instead the air travels along the path shown by arrows **85** through the other one-way valve of the connector and out the expiratory training tube **45**. In some embodiments, either of the valves **30** or **31** could be provided as a single valve that is bi-directional to permit airflow bi-directionally. In this way, in some embodiments a bi-directional valve is used that is within or adjacent to connector **27** that is adjustably configured (e.g., by rotatably) to close the second flow path when air moves along

the first flow path, and to close the first flow path when air moves along the second flow path.

[0043] Fig. 3 illustrates an exploded view of respiratory training device **5**. As shown in Fig. 3, mouthpiece **10** includes a mouthpiece flange **12** to receive the mouth of a user. Mouthpiece **10** connects to mouthpiece adapter **15**, which connects to connector **27** via mouthpiece port **40**. In some embodiments, the inspiratory training tube **42** and the expiratory training tube **45** are identical (and interchangeable) devices that permit the passage of air flow in one direction. In other embodiments, inspiratory training tube **42** and expiratory training tube **45** are different because the range of inhale and exhale pressures are different, as well as the respective pressure markings on the devices. When a training device is connected to the inspiratory training tube adapter **18**, which in turn connects to the connector **27** via inspiratory training tube port **38**, the training device only permits air flow into the respiratory training device **5** along path **82**. When a training device is connected to the expiratory training tube adapter **20**, which in turn connects to the connector **27** via expiratory training tube port **35** (best illustrated in Fig. 6), the training device only permits air flow out the respiratory training device along path **85**. Adapters (**15**, **18**, and **20**) are optional features and provided in Fig. 3 for illustrative (and non-limiting) purposes. Accordingly, a training device can be used for either inspiration or expiration, and its function will depend on whether the training device is connected to the inspiratory or expiratory side of connector **27**. In some embodiments, the inspiratory training tube **42** can only be used for inspiration and the expiratory training tube **45** can only be used for expiration because of the unique inhale and exhale pressures and the unique pressure markings on the respective tubes.

[0044] Fig. 3 also shows an exploded view of pressure sensor **62**, which includes female connector **65** (to receive and attach to the pressure sensor joint **25**) and pressure sensor

release valve **68**. In some embodiments, the pressure sensor **62** connects to the processing unit **101** via pressure sensor wire **72**. As best illustrated in Fig. 8, in some embodiments pressure sensor wire **72** includes a plug **73** that is received in plug receiver **110** of processing unit **101**. In other embodiments, the pressure sensor **62** and the other components of the respiratory training device **5** are wirelessly connected to another device.

[0045] For illustrative (and non-limiting) purposes, the present embodiments are described with a pressure sensor **62** having a molded body with a pressure sensing chip affixed into a compartment in the molded body. In some embodiments, this chip contains a micro-diaphragm that detects changes in pressure. The micro-diaphragm and flow path are separated by a “dielectric silicon” that 1) can transmit force (pressure) from the flow path to the micro-diaphragm while 2) providing isolation of the flow path from the micro-diaphragm. This sensor assesses a flow path opening of about ~4mm diameter that runs throughout the entire molded body. Furthermore, in some embodiments, the pressure sensor **62** operates by generating a voltage output that is proportional to pressure. However, any number of pressure sensors may be used as are well known to persons of ordinary skill in the art. According to current embodiments, a preferable pressure sensor is affordable, highly accurate, and light-weight.

[0046] Figs. 4 and 5 illustrate inspiratory training tube **42** and expiratory training tube **45**. For illustrative (and non-limiting purposes), inspiratory training tube **42** consists of Philips Respironics® Device HS735-010, Andover, MA and expiratory training tube **45** consists of Philips Respironics® Device HS730-010, Andover, MA. As previously noted, in some embodiments inspiratory training tube **42** and expiratory training tube **45** are identical and interchangeable, and their function in the respiratory training device **5** depends on whether the training device is connected to the inspiratory or expiratory side of connector **27**. In some

embodiments, the inspiratory training tube **42** can only be used for inspiration and the expiratory training tube **45** can only be used for expiration because of the unique inhale and exhale pressures and the unique pressure markings on the respective tubes.

[0047] As illustrated in Figs. 4 and 5, in some embodiments, inspiratory training tube **42** and expiratory training tube **45** comprise neck **48**, screw **50**, screw handle **51**, disc **52**, spring **55**, and one-way valve **60** with a seal **58**. When used with the inspiratory training tube **42**, one-way valve **60** is referred to as an inspiratory valve. Likewise, when used with the expiratory training tube **45**, one-way valve **60** is referred to as an expiratory valve. In some embodiments, the outside of the tub includes gradations of the pressure values (e.g. in units of cm H₂O) and disc **52** illustrates the pressure resistance level within the training device. Spring **55** is connected to the seal **58** of one-way valve **60**, and thus spring **55** applies pressure to the one-way valve **60**. In some embodiments, inspiratory training tube **42** and expiratory training tube **45** comprise an end portion **46** with a diameter (D1) and an expanded portion **47** with a larger diameter (D2) than D1. In some embodiments, the diameter of seal **58** is larger than D1 but smaller than D2.

[0048] In some embodiments, a user can adjust the pressure settings of inspiratory training tube **42** and expiratory training tube **45** by manual manipulation of compression springs inside the airway valves. To adjust the pressure settings, a user first removes neck **48** and manually rotates screw handle **51** of screw **50** to adjust the compression of spring **55**, which in turn moves the disc **52** up or down the pressure gradations which can be marked on the outside of the tube. As spring **55** becomes more compressed, the pre-compressed position of spring changes as the distance from a non-fixed end of the spring is shortened relative to the position of the other, fixed end of the spring. In this way, the force generated by the spring on the one-way valve **60** increases, and thus higher pressure is required to open one-way

valve **60**. This relationship between the compression of the spring **55**, the force on the one-way valve **60**, and the pressure required to open the valve is explained by Hooke's law (Equation 1), which is:

[0049] $F = -k * X$ (Equation 1)

[0050] where "F" is force, "X" is displacement or change in distance from a non-fixed end of a spring to its other, fixed end, and "k" is a constant that is characteristic of the particular spring (sometimes expressed as a negative value in the context of a restoring force exerted by a spring). Accordingly, Equation 1 describes how restoring force F scales linearly with respect to that distance the spring is either compressed or extended. The negative sign in front of the constant indicates that the equilibrium force is in the opposite direction of the displacement, X. As X decreases, the spring compresses, which increases the force on one-way valve **60**. When this compressive force increases, a greater force is required during breathing exercises to open the one-way valve **60**.

[0051] Accordingly, the larger force applied over the surface area of the one-way valve **60** is known as the "cracking pressure" at which point a valve begins to open and pass fluid or air. In turn, as spring **55** becomes elongated (i.e. less compressed), less pressure is required to open one-way valve **60**. In either case, flow is established through inspiratory training tube **42** and expiratory training tube **45** when an enough force is generated to overcome the force created by spring **55**. When the valve opens, seal **58** of one-way valve **60** is no longer in contact with end portion **46** and air can pass through. Once flow is established through the one-way valve **60** such that seal **58** is no longer in contact with end portion **46**, the valve continuously remains open as long as the force from the air flow remains above the restorative force created by spring **55**. An increased pressure setting requires increased effort from the user to open the seal **58** of one-way valve **60**, and this increasing difficulty

represents a fundamental basis of improving respiratory performance. One of ordinary skill in the art will appreciate that various kinds of valves may be selected and used for one-way valve **60**, such as a butterfly valve.

[0052] As illustrated in Figs. 10 and 11, in some embodiments processing unit **101** includes a valve controller **140** that can be adjusted by the user to change the resistance level in the inspiratory training tube **42** and expiratory training tube **45**, i.e., to increase or decrease resistance. In this embodiment, the valve controller **140** is electromechanically connected to adjustable valve **122**. A user changes the resistance level by manually entering the threshold pressure setting into processing unit **101** through user interface **155**, and the valve controller **140** changes the adjustable valve to the user's input entry accordingly.

[0053] As shown in Fig. 6, connector **27** includes pressure port **32**, expiratory training tube port **35**, inspiratory training tube port **38**, and mouthpiece port **40**. For illustrative (and non-limiting purposes), an exemplary connector **27** is a Carefusion® (Skokie, Illinois) U/Adapt-IT "T" Part Number 004051. Pressure port **32** receives pressure sensor adapter **22**, which is connected to pressure sensor **62** via pressure sensor joint **25**. Inspiratory training tube port **38** receives inspiratory training tube adapter **18**, which connects to inspiratory training tube **42**. Expiratory training tube port **35** receives expiratory training tube adapter **20**, which connects to expiratory training tube **45**. Mouthpiece port **40** receives mouthpiece adapter **15**, which connects to mouthpiece **10**. Adapters (**15**, **18**, and **20**) are optional features and provided in Figs. 3 and 6 for illustrative (and non-limiting) purposes. Connections between various parts described in this paragraph can be established through one of various techniques as known in the art, one example being forming portions of these parts to join together in an interference fit.

[0054] As previously noted, in some embodiments connector **27** includes one-way valve **30** and one-way valve **31** (best illustrated in Fig. 2) that permit air to travel only through the inspiratory training tube **42** or out the expiratory training tube **45**, but not both. The position of pressure port **32** in tee connector **27** permits the pressure sensor **62** to monitor and detect the pressure level when the user both inhales or exhales through respiratory training device **5**.

[0055] Figs. 7 and 8 show a processing unit **101** according to multiple embodiments and alternatives. Processing unit **101** includes enclosure **105**, USB port **108**, touchscreen **102**, plug receiver **110**, and memory card slot **112** (not shown). In some embodiments, USB port **108** receives an external transmission wire **70** with a USB plug **71** that can attach to a computer or other device. Any number of ports can be built into processing unit **101** as are well known to persons of ordinary skill in the art. For users with spinal cord injuries that cannot easily manipulate their hands and fingers, touchscreen **102** is helpful in reviewing pressure activity during a training session, the results of the training session and controlling respiratory training device **5**. In addition, in some embodiments the processing unit **101** provides audible feedback to the user. Conventional respiratory training devices are typically rudimentary and provide no feedback to the user. On the other hand, the processing unit **101** according to current embodiments provides visual and audio feedback to inform the user of their training level, which is a key component in implementing a training protocol. In some embodiments, the processing unit **101** converts the voltage output generated by the pressure sensor **62** to a pressure value that represents the air pressure data transmitted to the processing unit. In some embodiments, processing unit **101** also calculates the user's respiratory rate from the generated air pressure data. The respiratory rate is the rate at which breathing occurs and is usually measured in breaths per minute.

[0056] As will be discussed in more detail below, in some embodiments the control device system **100** contains hardware and software features that provide for data acquisition, recording, storage, retrieval and display functions for airway pressure monitoring data to provide functional evaluation, progress monitoring, and diagnostic features.

[0057] The respiratory training device **5** provides a mode to calculate a user's maximum expiratory pressure (MEP) and maximum inspiratory pressure (MIP), and a respiratory training mode as the user inhales and exhales through the breathing apparatus. The MEP refers to the maximum pressure that a user can generate when exhaling and MIP refers to the maximum pressure generated by a user when inhaling. To obtain a user's MEP value, attachment **75** (shown in Fig. 9) is attached to expiratory training tube port **35** and control device system **100** guides the user through this mode to obtain the MEP value. To obtain the MIP value, attachment **75** is attached to inspiratory training tube port **38** and control device system **100** guides the user through this measurement. According to present embodiments, attachment **75** (shown in Fig. 9) can be connected to respiratory training device **5** to measure and record the maximum pressures of inhalation and exhalation that a user can produce. In some embodiments, attachment **75** includes first member **76**, second member **77**, adjustable valve **78** and extension **80** to attach to connector **27**. In some embodiments, attachment **75** only permits the passage of air in one direction, it restricts air flow, and facilitates collection of airway pressure data a user produces.

[0058] As discussed below, training target pressure values for the respiratory training mode may be developed from the MEP and MIP values. In the respiratory training mode, the user inhales and exhales through respiratory training device **5** with both the inspiratory training tube **42** and expiratory training tube **45** attached. In this mode, the respiratory training device **5** functions like a spirometer, which is a device for measuring the volume of

air inhaled and exhaled through the lungs. In the training mode, the inspiratory training tube **42** and expiratory training tube **45** are manually adjusted to match training target pressure values determined from the MEP/MIP mode. While performing the respiratory training mode, a user inhales and exhales through respiratory training device **5**, cracking one-way valves **60**, and works to maintain set target pressure values. The user interface of control device system **100** provides visual feedback to the user during training mode, and in some embodiments it lights on-screen LEDs if the user is reaching the training target values.

[0059] Fig. 10 is a block diagram depicting the data acquisition, recording, storage, retrieval and display functions of control device system **100**, according to multiple embodiments and alternatives. The portion of Fig. 10 associated with airflow tube **120** (i.e., a portion of a respiratory training device through which air travels and is monitored, such as inspiratory training tube **42**, expiratory training tube **45**) depicts one or more volumes within which are positioned one or more sensors **125** which may include pressure sensor **62** as a non-limiting example). Such sensors generate sensor readings **135** which measure and track conditions inside an airflow tube **120**.

[0060] In some embodiments, user interface **155** depicts the component that provides a visual output to the user and receives user input. As a non-limiting example, touchscreen **102** serves as a user interface in the embodiments illustrated in Fig. 1. As illustrated in Figs. 13-20, user interface **155** guides users through various training sessions, displays results, and receives input from the user. As desired, an app may be provided that can be downloaded and executed upon a smart phone, tablet, personal computer, laptop, mobile device or similar device that guides the user, controls the respiratory device, and keeps track of performance and progress.

[0061] The block associated with processing unit **101** depicts the processing unit within which is positioned power management **138** to provide power to the processing unit **101** and respiratory training device **5** (such as battery powered, plugged into an outlet, etc.). Optionally, a power source for one or both of these components is a rechargeable lithium-ion battery. In some embodiments, processing unit **101** is configured to write and record time-stamped MEP/MIP and training data to local storage (e.g., microSD memory card) for later retrieval, and switch into sleep mode between uses to save power. Various alternative forms of memory as known in the art can be used for storage. In current embodiments, processing unit **101** includes valve controller **140** which is electromechanically connected to adjustable valve **122**. A user can change adjustable valve **122** by manually inputting a particular resistance value into user interface **155**, which in turn causes the valve controller **140** to change adjustable valve **122**. Such a sequence could be programmed into the user interface on a screen. For example, an actuator (not shown) may be assigned to each adjustable valve **122** and will respond to electronic commands from a processor, microprocessor, or microcontroller connected to the processing unit **101**, which execute computer-readable program instructions or suitable program logic. In some embodiments, a first actuator is positioned to adjust the inspiratory valve to change a first resistance to movement of air along the first flow path and a second actuator is positioned to adjust the expiratory valve to change a second resistance to movement of air along the second flow path.

[0062] As reflected in Fig. 10, processing unit **101** may include protocol instructions **142** to control the various functions of the respiratory training device **5**, such as receiving and processing user input, guiding a user through a therapy session with prompts, informing user interface **155** to display results and device functions, and so forth. In some embodiments, processing unit **101** may also include a real-time clock (not shown) to record the date and time when a user utilizes the device, and to assist the user in monitoring their progress over

time. Processing unit **101** consists of memory **148** to record and store therapy sessions and provide various processing unit **101** functions. As previously noted, in current embodiments respiratory training device **5** includes two modes: a MEP/MIP mode which generates MEP/MIP values **150** and a training session that generates training session data **151**. Processing unit **101** is involved with providing digital output via a network through a wired connection or wireless module **145**.

[0063] As shown in Fig. 11, in some embodiments control device system **100** includes an airflow tube **120** positioned within a processing unit **101** which wirelessly communicates with a remote controller **160**. In Fig. 11, airflow tube **120** includes adjustable valve **122** and pressure sensor **125**. The sensor readings **135** generated by one or more sensors are sent to valve controller **140** positioned within processing unit **101**. In some embodiments, a user can change adjustable valve **122** by manually providing input via user interface **155** of remote controller **160**. In some embodiments, user input is in turn wirelessly communicated to valve controller **140** that is connected to electromechanically adjustable valve **122**. In some embodiments, a low-power, energy-conserving, battery-powered microcontroller, or like components, is located within or operationally connected to the bi-directional airflow assembly **8** for storing and executing program code to initiate actuation of each valve **60**. Processing unit **101** also includes power management **138** and wireless module **145** to provide wireless communication with remote controller **160**. As a non-limiting example, remote controller **160** is a mobile phone or a tablet with an app programmed to wirelessly communicate with processing unit **101**. In Fig. 11, remote controller **160** includes protocol instructions **142**, wireless module **145**, memory **148**, and user interface **155**. In current embodiments, remote controller **160** produces MEP/MIP values **150** and training session data **151**.

[0064] Fig. 12A-12C illustrate the operation processes of the respiratory training device **5** utilizing control device system **100**, according to multiple embodiments and alternatives. Figs. 13-20 illustrate various user interface displays of the operation processes on a touchscreen display (as a non-limiting example). The various user interface displays illustrate the visual output of the device and user input of the respiratory training device **5** utilizing control device system **100**, according to multiple embodiments and alternatives. It will be appreciated that the scope of embodiments is not limited to and does not otherwise require the arrangement of components illustrated in Figs. 10 and 11, is not limited to and does not otherwise require the operation processes illustrated in Fig. 12A-12C, and is not limited to the user interface displays illustrated in Figs. 13-20.

[0065] As shown in Fig. 12A-12C, after the respiratory training device **5** is turned on (**200**), step **210** is for performing an initialization process to verify the real-time clock is functioning and a memory card (such as an SD card) is inserted into memory card slot **112**. Once the checks at step **210** pass, the user is notified to press “Start” at step **220** (see user interphase illustrated at Fig. 13). On the Directory page (see Fig. 14), the respiratory training device **5** runs an initial calibration step (**220**) to zero any initial pressure sensor offsets which account for the current location of the device and environmental effects on pressure sensor **62**. After step **220**, the user presses “Make File Session” at step **230** to create a new file for the current session (see Fig. 14). Next, the device performs a file-check on file names that exist in the memory (step **240**). If previous data does not exist (**250**), the device creates a new file and starts numbering files with 01 (step **255**). If previous data does exist, the device proceeds to step **260** and creates a new file with the most subsequent number. At step **270**, the respiratory training device **5** reads the previous data file and inputs those previous pressure values from the memory file to LED digit displays throughout the device (see e.g.

Fig. 18). At step **280**, the user must select if they want to proceed with the MEP/MIP mode or training mode (see Fig. 14).

[0066] As shown in Fig. 12B, if the user proceeds with the MEP/MIP mode (e.g. by selecting the “MEP/MIP” virtual button shown in Fig. 14), the user is moved to “% Training Setting” at step **290**, selects a multiplier for the MEP/MIP mode and then presses “Next” to conduct the diagnostic test (e.g. see “Next” virtual button in Fig. 15). In some embodiments, the user selects the multiplier by adjusting a “Training % Slider” virtual button illustrated to the right of the “Training % Setting” and “Previous % Setting” in Fig. 15. According to multiple embodiments and alternatives, the purpose of a “Training % Slider” is to set the multiplier for the MEP/MIP mode which will generate the target pressures that the user needs to reach in the training mode. For example, if the MEP is 100 psi and the user wants to train at 20%, the device will change the target pressure to 20 psi. While a user can select any training percentage, a clinician or anyone who understands how to strengthen respiratory muscles, will know the optimal training percentage of MEP/MIP that a user should select to improve respiratory fitness during training. In some embodiments, the MEP/MIP values **150** are relayed to the clinician who then informs the user what resistance to select on the manual resistance valves of the inspiratory training tube **42** and the expiratory training tube **45**.

[0067] On the MEP/MIP page (illustrated in Fig. 16), the user will select the button to conduct the MEP or MIP test (**300**). In a clinical setting, a clinician prepares the respiratory training device **5** with the attachment **75** and instructs the user on how to inhale or exhale for the test. In a home setting, the respiratory training device **5** provides instructions to the user on connecting attachment **75** and conducting the MEP/MIP tests. Once attachment **75** is connected, the clinician or user will press “MIP” (see Fig. 16) and follow the instructions on when to inhale. Once the inhalation test is complete, the clinician or user will switch

attachment **75** to the expiratory side, and instruct the user on how to exhale through the apparatus. Either the clinician or user can press “MEP” to begin the test (see Fig. 16). Step **310** is for calculating the data from the MEP/MIP test and displaying the results from the calculation on the user interface (see Fig. 17). On the “Results” page illustrated in Fig. 17, the user interface displays MEP and MIP values from the test and the calculated training values for the training mode from the “% Training Setting” inputted by the user. From the “Results” page, the user presses a button to return to “Directory” page (**320**).

[0068] As shown in Fig. 12B, the user can press “Training” on the “Directory” page to begin the training mode (**330**). In some embodiments, training values are displayed next to LED indicators to provide additional visual output to the user (see e.g. Fig. 18). For example, in non-limiting embodiments the LED indicators light up green if the user’s current pressure reading reaches 90% of the training value. Furthermore, a user can adjust the training values by adjusting a sliding gauge (illustrated at Fig. 19), which provides additional visual feedback for the user during the training session.

[0069] At step **340**, the clinician or user will manually change the resistance settings on the inspiratory training tube **42** and the expiratory training tube **45** to match the training values. The clinician or user will then detach attachment **75** and attach both the inspiratory training tube **42** and the expiratory training tube **45** as best illustrated in Figs. 1 and 3. Before beginning the training session, the user or clinician selects the duration of the training session and presses the corresponding button on the user interface display (**340**). In the embodiments illustrated in Fig. 18, a user can select between 3 to 5 minute training sessions, however it will be appreciated that any length of time for a training session may be selected. Once the timer is set, at step **350** the user presses “Start” (see virtual button shown in Fig. 18) to begin the training session.

[0070] During the training session, live pressure readings are displayed on the user interface display and saved to the memory (360). The user inhales and exhales through the respiratory training device 5 to meet the pressure goals calculated from the MEP/MIP mode (370). Once the timer ends, at step 380 the pressure recording embodiments cease. Next, the user can repeat a training session (390). If the user desires to repeat a training session using the same time (395), the user can press the “Start” button to begin the training again (350). Alternatively, the user can select a new interval (375) and begin a new training session (350).

[0071] Once training is complete, the user presses “Results” (see virtual button illustrated in Fig. 18) to view the results of the training (400). On the “Results” page (see Fig. 20), the user interface displays the results from the current training session (410) and the results from previous training sessions by retrieving data from previous file (420). In some embodiments illustrated in Fig. 20, the “Results” page displays the date, time, highest exhale, lowest inhale, the MEP, the MIP, and the training percentage from the current session and the previous session in a second column. However, any number of results may be displayed as are well known to persons of ordinary skill in the art. Next, the user turns the device off (430) and stores it away until the next training session.

[0072] Fig. 21 illustrates example results of a user training session with a respiratory training device 5, wherein the x column represents the time in seconds of the training session and the y column represents the pressure values in units of cm H₂O. As shown in Fig. 21, the respiratory training device 5 records, monitors and displays the inspiratory and expiratory pressure as the user breathes through the device. In this particular example, the length of the user’s inhale and exhale greatly diminished after roughly 9 seconds of training on the device. These types of results can be used to monitor and implement respiratory training regimens.

Example 1 – Verification and Validation

Pressure Test

[0073] To verify and validate the respiratory training device 5, pressure measurements using the device were compared to a Delta-Cal Transducer Similar and Tester (Utah Medical Products, Salt Lake City, UT). The Delta-Cal tester was connected directly to pressure sensor 62 and pressure adjusted to compare with the pressure measurements in respiratory training device 5. Measurements were recorded every five minutes, for twenty minutes to characterize any drift in the measurement. Both the Delta-Cal and the respiratory training device 5 readings were recorded for comparison and device validation.

[0074] Table 1 provides the averages of data points (n=5) obtained for pressure measurements using respiratory training device 5. The average standard deviation of the respiratory training device 5 pressure measurement versus Delta-Cal measurement was 1.16 mmHg (n=11). Average percent error of the respiratory training device 5 measurements versus calibrator was 3.44% across the span of pressures measured. This percent error is larger than the 2% accuracy range rated by pressure sensor's manufacturer that covered an even larger range (0-310.29 mm Hg) versus bench testing (-50 to 50 mm Hg). This error was deemed acceptable as errors could have stemmed from calculation errors in the software.

Table 1. Statistics of Average Respiratory Training Device Measurements Compared to Delta-Cal Measurements

Delta-Cal (mmHg)	Average BF (mmHg)	Std. BF	% Error
-50	-48	2.33	4.12
-40	-38	1.97	4.41
-30	-29	1.48	4.41
-20	-19	0.89	3.68
-10	-10	0.49	4.41
0	0	0.00	0.00
10	10	0.49	4.41

20	19	0.77	2.94
30	29	0.89	2.45
40	38	1.84	4.04
50	49	1.64	2.94
Average		1.16	3.44

Analysis of Pressure Sensor Test

[0075] The respiratory training device **5** produced a near 1:1 relationship compared to the Delta-Cal pressure standard in the pressure sensor test. Despite an average standard deviation of 1.16, and percent error of 3.44%, the larger standard deviation occurred mostly in the higher-pressure ranges of 30-50 mmHg, consistent with most common pressure and force sensors with accuracies reported as a percent of full scale. The farther the measurement from zero, the larger the error. Regardless, these larger values of pressures exceed normal inspiratory and expiratory training regimens set by the training procedures discussed herein. Regular training settings for subjects with spinal cord injury usually range from 5-20 mmHg for both expiratory and inspiratory activates. When considering only that range, deviation average drops to 0.53 and percent error falls to 3.09%. With an R-squared of greater than 0.99, it can be confidently claimed that the pressure sensor used in the respiratory training device **5** and the conversion calculations in the processing unit **101** produce accurate pressure readings regardless of the state of the sensor and produce similar results to that of the calibrated pressure reference device.

Example 2 – Subject Testing

[0076] As shown in table 4, subject testing was conducted to verify the respiratory training device **5** fulfills its intended purposes as discussed herein. During this test, a volunteer (Subject A) with lower extremity paralysis was used to obtain subject data. During the test, Subject A had pressure threshold settings set to 10% of their individual MEP/MIP. Subject A

performed two 10% threshold sessions. Table 4 shows the results of expiratory and inspiratory training of subject A. Deviation of expiratory pressure was calculated by finding the average pressure of all complete expiratory cycles and subtracting it from the target expiratory pressure. The deviations of inspiratory pressures were calculated in the same way.

Table 4. Subject A Data

	Summary of Participant Data		
	10%		
MEP	93.00	93.00	
Target Exp	9.30	9.30	Average
Average Exp	8.77	7.97	8.37
Deviation	-0.53	-1.33	-0.93
MIP	-94.00	-94.00	
Target Insp	-9.40	-9.40	Average
Average Insp	-8.23	-7.06	-7.65
Deviation	1.17	2.34	1.76

[0077] Because the pressure sensor was validated previously by Delta-Cal, it was safe to assume that pressure values displayed on the respiratory breathing device **5** were accurate. After MEP/MIP tests were conducted, threshold valve levels were set to match target values derived from MEP/MIP.

[0078] Accordingly, the results from Example 2 illustrate the respiratory training device **5** functions for its intended purposes and provides respiratory muscle training.

[0079] It will be understood that the embodiments described herein are not limited in their application to the details of the teachings and descriptions set forth, or as illustrated in the accompanying figures. Rather, it will be understood that the present embodiments and

alternatives, as described and claimed herein, are capable of being practiced or carried out in various ways.

[0080] Also, it is to be understood that words and phrases used herein are for the purpose of description and should not be regarded as limiting. The use herein of “including,” “comprising,” “e.g.,” “containing,” or “having” and variations of those words is meant to encompass the items listed thereafter, and equivalents of those, as well as additional items.

[0081] Accordingly, the foregoing descriptions of several embodiments and alternatives are meant to illustrate, rather than to serve as limits on the scope of what has been disclosed herein. The descriptions herein are not intended to be exhaustive, nor are they meant to limit the understanding of the embodiments to the precise forms disclosed. It will be understood by those having ordinary skill in the art that modifications and variations of these embodiments are reasonably possible in light of the above teachings and descriptions.

CLAIMS

What is claimed is:

1. A respiratory device for training a user's respiratory fitness, comprising:

a bi-directional airflow assembly comprising an inspiratory training tube, an expiratory training tube, a connector, and a mouthpiece, wherein each of the inspiratory training tube, expiratory training tube, connector, and mouthpiece has a hollow portion;

wherein the connector establishes a first flow path through the hollow portions of the mouthpiece and the inspiratory training tube, and the connector establishes a second flow path through the hollow portions of the mouthpiece and the expiratory training tube;

wherein the inspiratory training tube comprises an inspiratory valve permitting air entry into the inspiratory training tube, and the inspiratory training tube, connector, and mouthpiece define a first volume representing the first flow path for air drawn into the bi-directional airflow assembly when the user inhales through the mouthpiece;

wherein the expiratory training tube comprises an expiratory valve permitting air to exit from the expiratory training tube, and the expiratory training tube, connector, and mouthpiece define a second volume representing the second flow path for air blown out of the bi-directional airflow assembly when the user exhales into the mouthpiece;

the bi-directional airflow assembly further comprising:

a first actuator positioned to adjust the inspiratory valve to change a first resistance to movement of air along the first flow path,

a second actuator positioned to adjust the expiratory valve to change a second resistance to movement of air along the second flow path;

a pressure sensor in communication with the volumes defined by the first flow path and the second flow path to obtain an air pressure data within the bi-directional airflow assembly associated with the user inhaling through, or exhaling into, the mouthpiece; and

a processing unit configured to receive the air pressure data from the pressure sensor, connect to a display device, and transmit the air pressure data to the display device.

2. The respiratory device of claim 1, wherein the connector comprises a first valve and a second valve arranged to close the second flow path when air moves along the first flow path, and to close the first flow path when air moves along the second flow path.

3. The respiratory device of claim 1, wherein the air pressure data is chosen from the group consisting of an inhale pressure, an exhale pressure, a date, and a time.

4. The respiratory device of claim 1, wherein the display device the processing unit is configured to connect to is chosen from the group consisting of a smartphone, a tablet, a personal computer, a laptop or a mobile device.

5. The respiratory device of claim 1, wherein the inspiratory training tube and the expiratory training tube are detachable from the connector.

6. The respiratory device of claim 5, further comprising an attachment for measuring a maximum exhale pressure when the user exhales through the mouthpiece and a maximum inhale pressure when the user inhales through the mouthpiece.

7. The respiratory device of claim 6, wherein a user inputs a training value into the processing unit prior to measuring the maximum exhale pressure and the maximum inhale pressure.

8. The respiratory device of claim 7, wherein a user inputs a training session duration into the processing unit prior to beginning the training session.

9. The respiratory device of claim 7, wherein the processing unit is configured to transmit live air pressure data and the results of the training session in a format that is displayed from the display device both visually and audibly.

10. The respiratory device of claim 1, wherein the air pressure data is a voltage output sensed by the pressure sensor, and the processing unit converts the voltage output to a pressure value representing the air pressure data transmitted to the display device.

11. The respiratory device of claim 1, wherein the processing unit is configured to receive user input, to display prompts guiding a user through a training session with the respiratory device, and to display live air pressure data during the training session.

12. The respiratory device of claim 1, wherein each of the first actuator and the second actuator changes the compression of a spring attached to one of the inspiratory valve or the expiratory valve, thereby changing a force applied to one of the inspiratory valve or the expiratory valve by said spring.

13. The respiratory device of claim 12, further comprising at least one screw that turns in response to manual rotation, thereby causing the first actuator or second actuator to change the compression of said spring and said force applied to one of the inspiratory valve or the expiratory valve by said spring.

14. The respiratory device of claim 1, wherein the processing unit is configured to send electronic commands to at least one of the first actuator and second actuator that adjust at least one of the first actuator and the second actuator in response to user input.

15. The respiratory device of claim 1, further comprising a bi-directional valve to close the second flow path when air moves along the first flow path, and to close the first flow path when air moves along the second flow path.

1/23

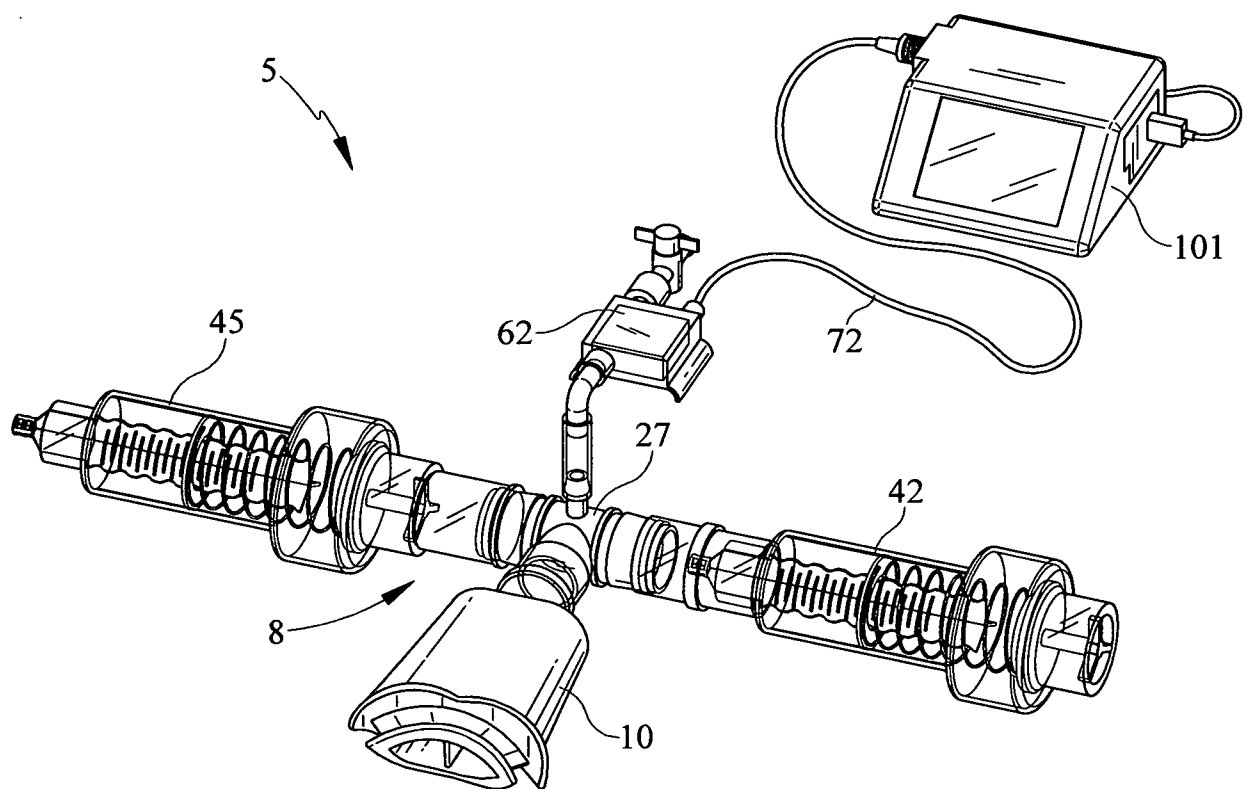


Figure 1

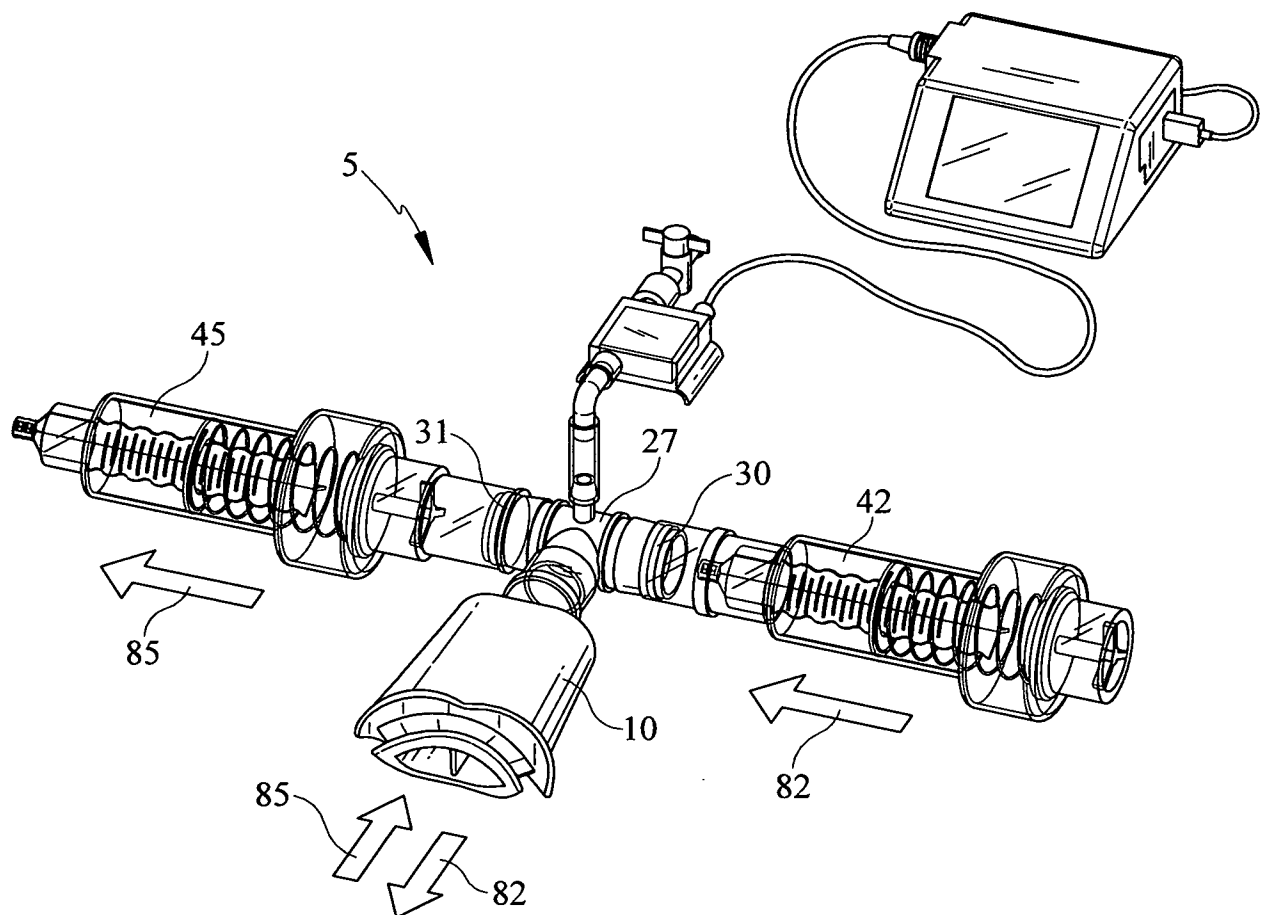


Figure 2

3/23

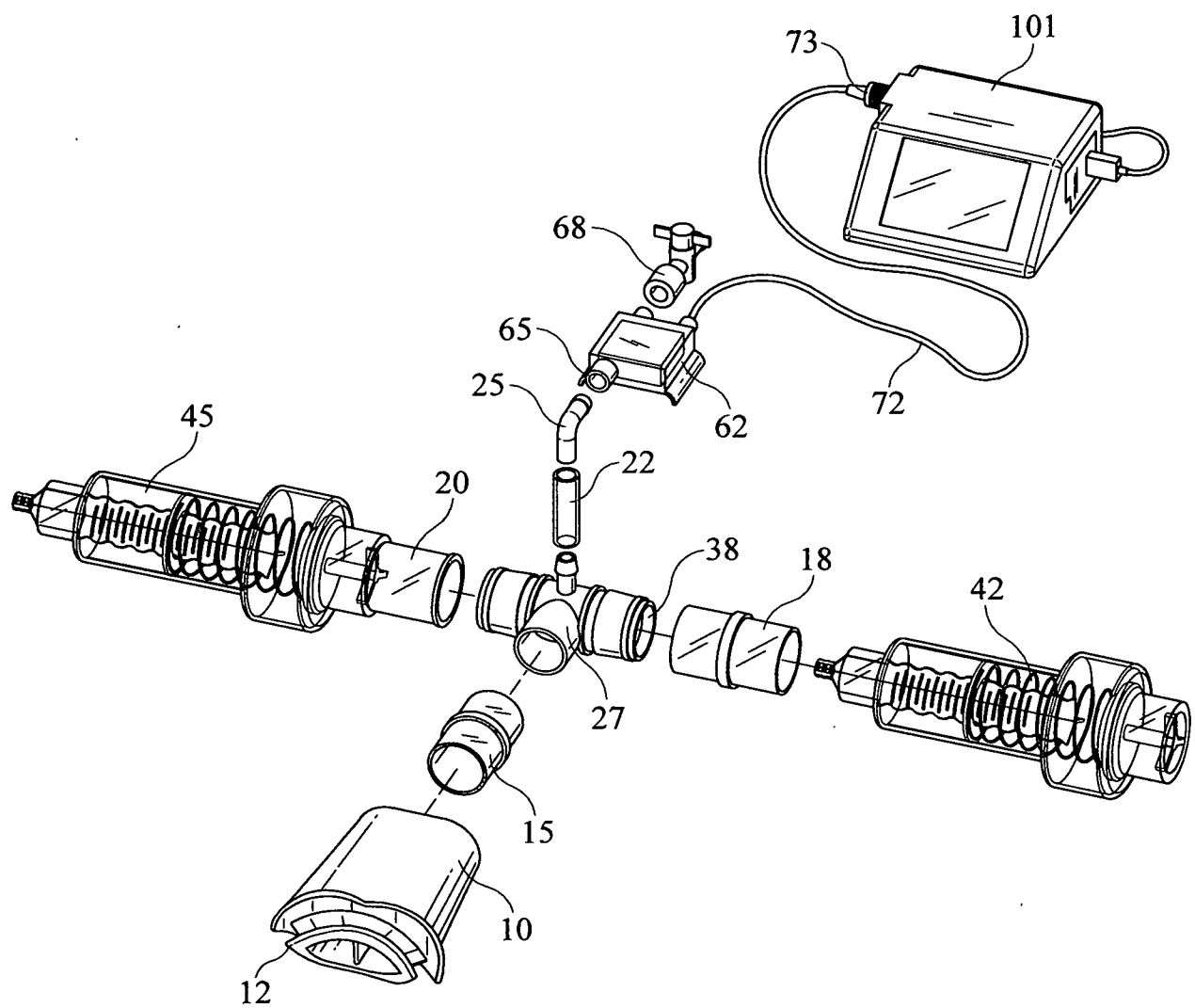


Figure 3

4/23

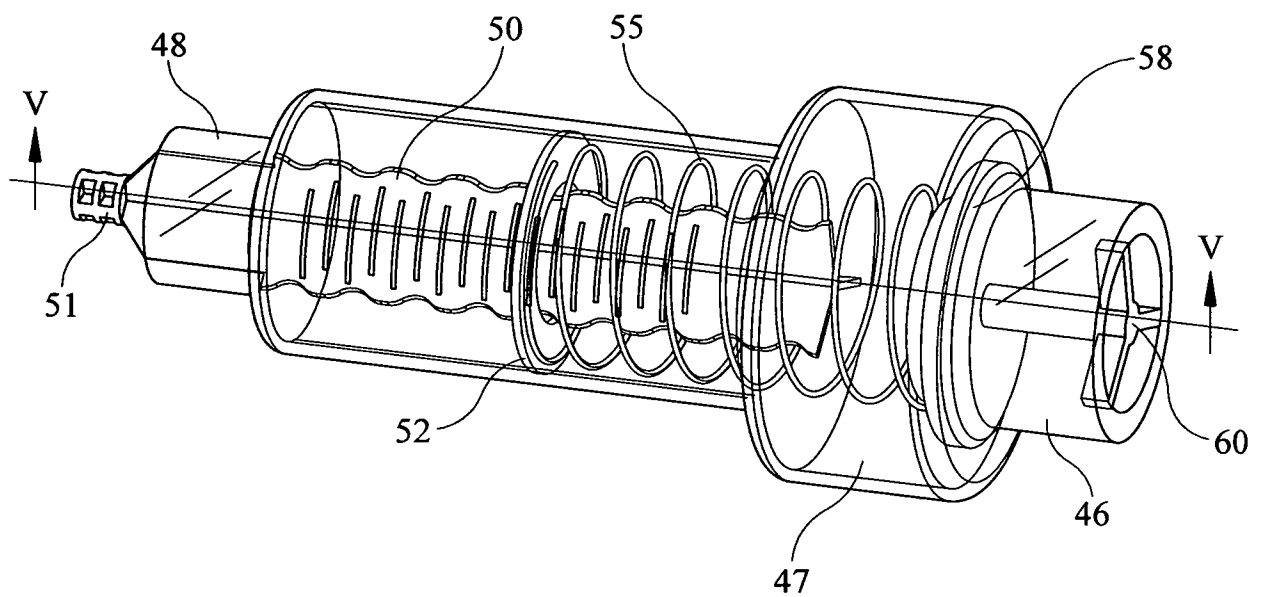


Figure 4

5/23

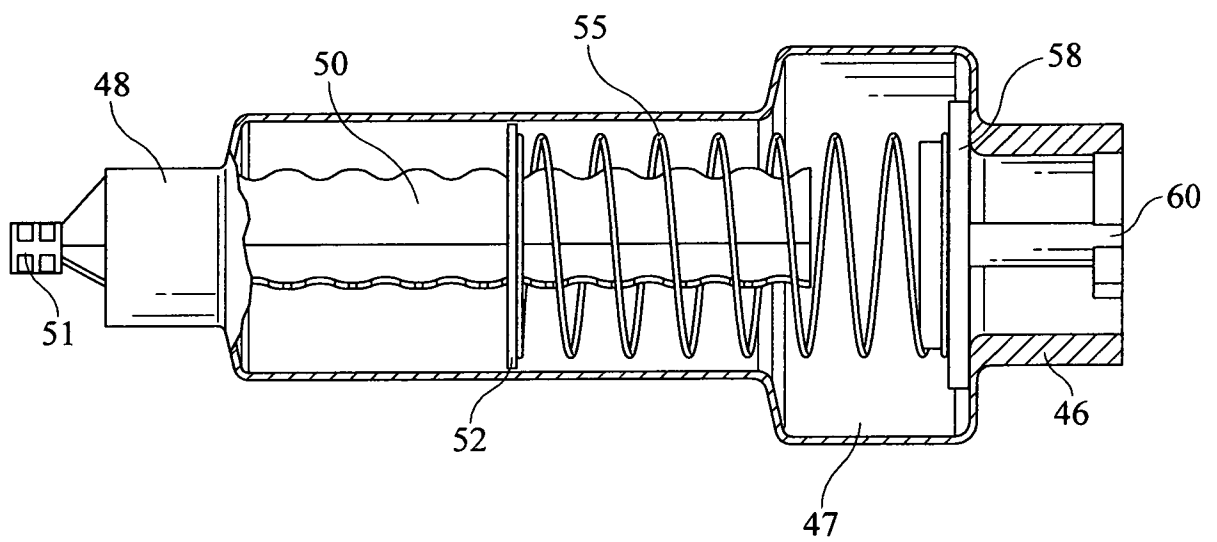


Figure 5

6/23

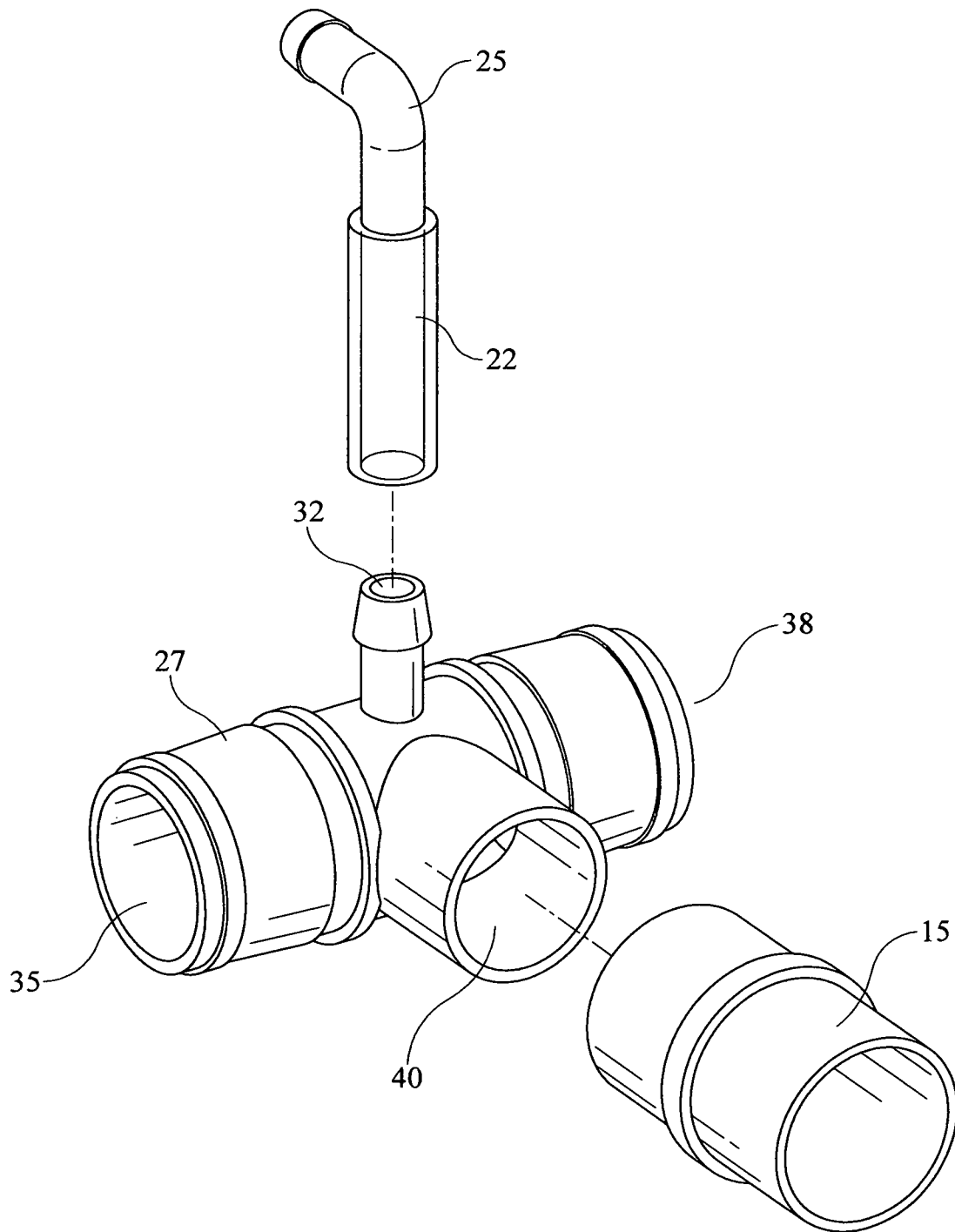


Figure 6

7/23

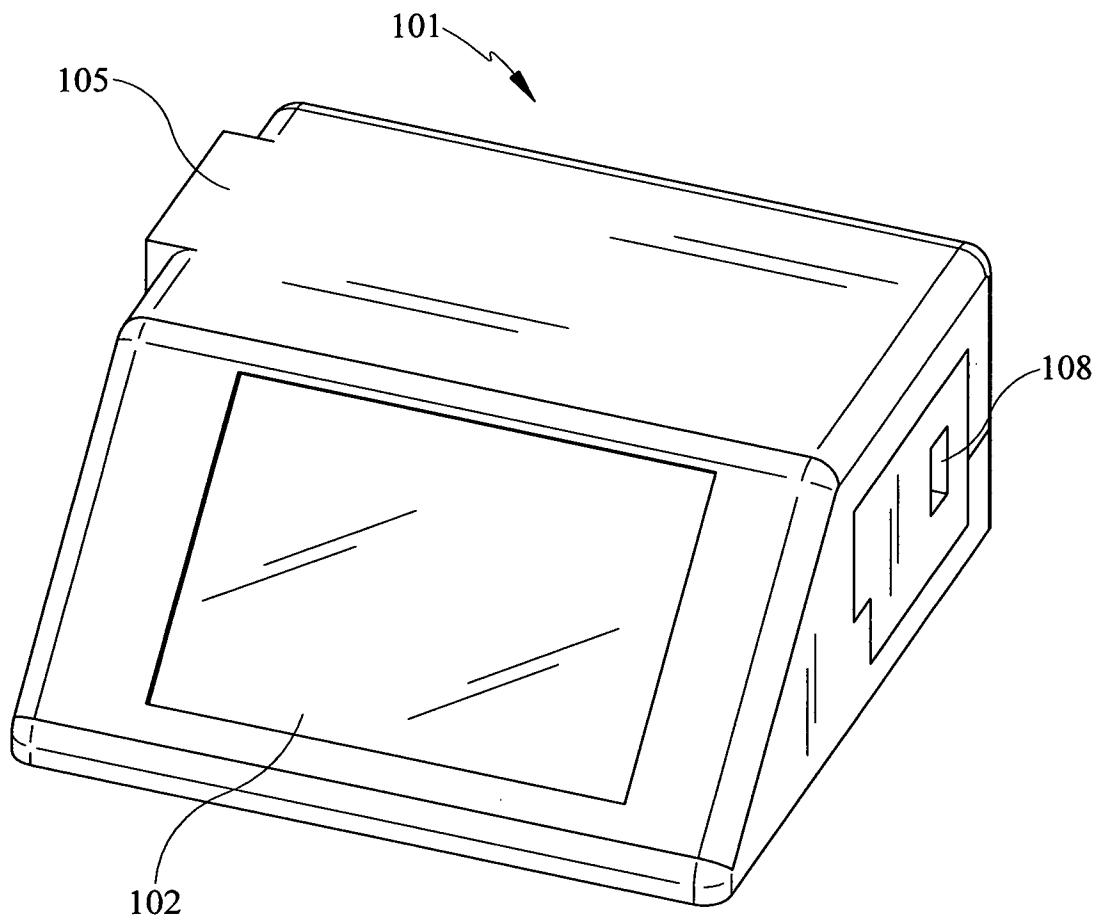


Figure 7

8/23

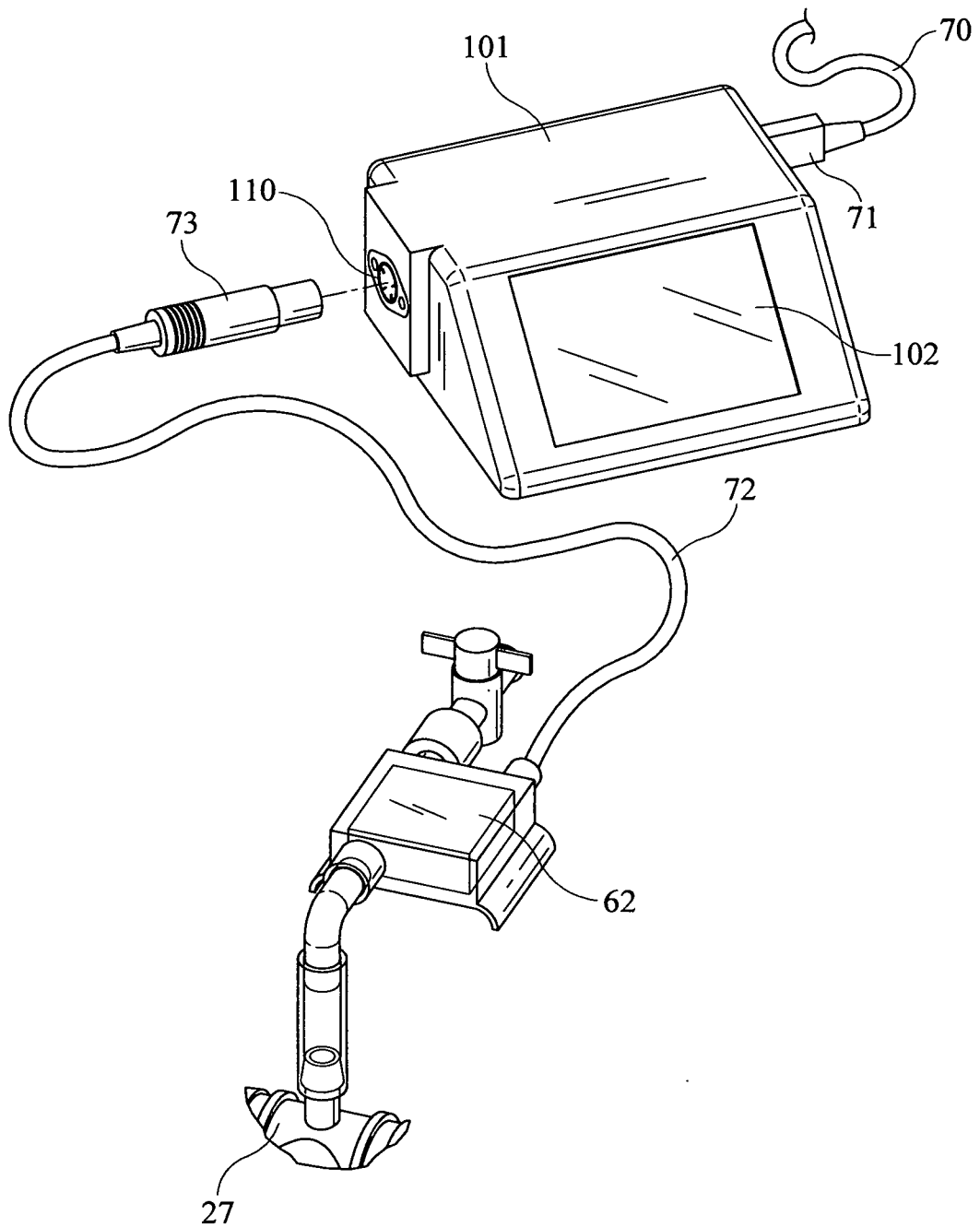


Figure 8

9/23

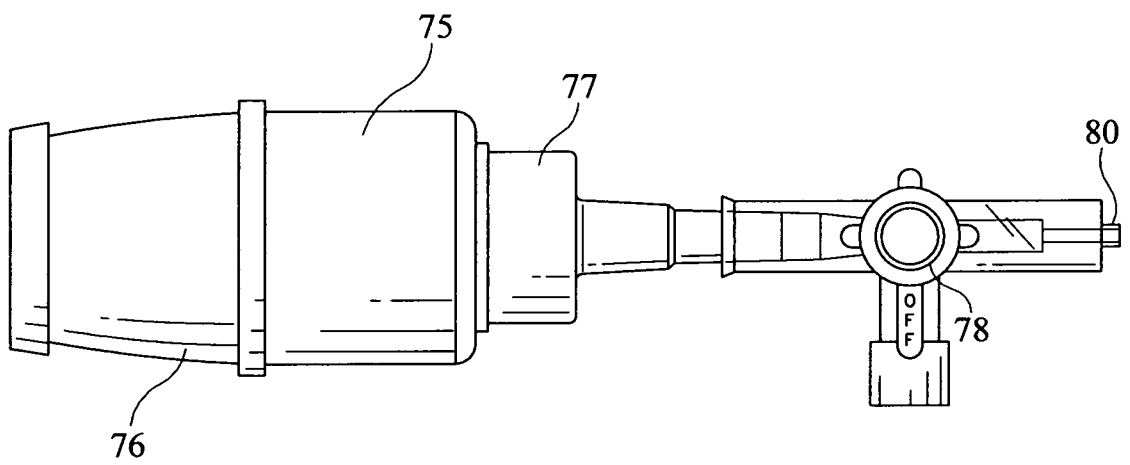


Figure 9

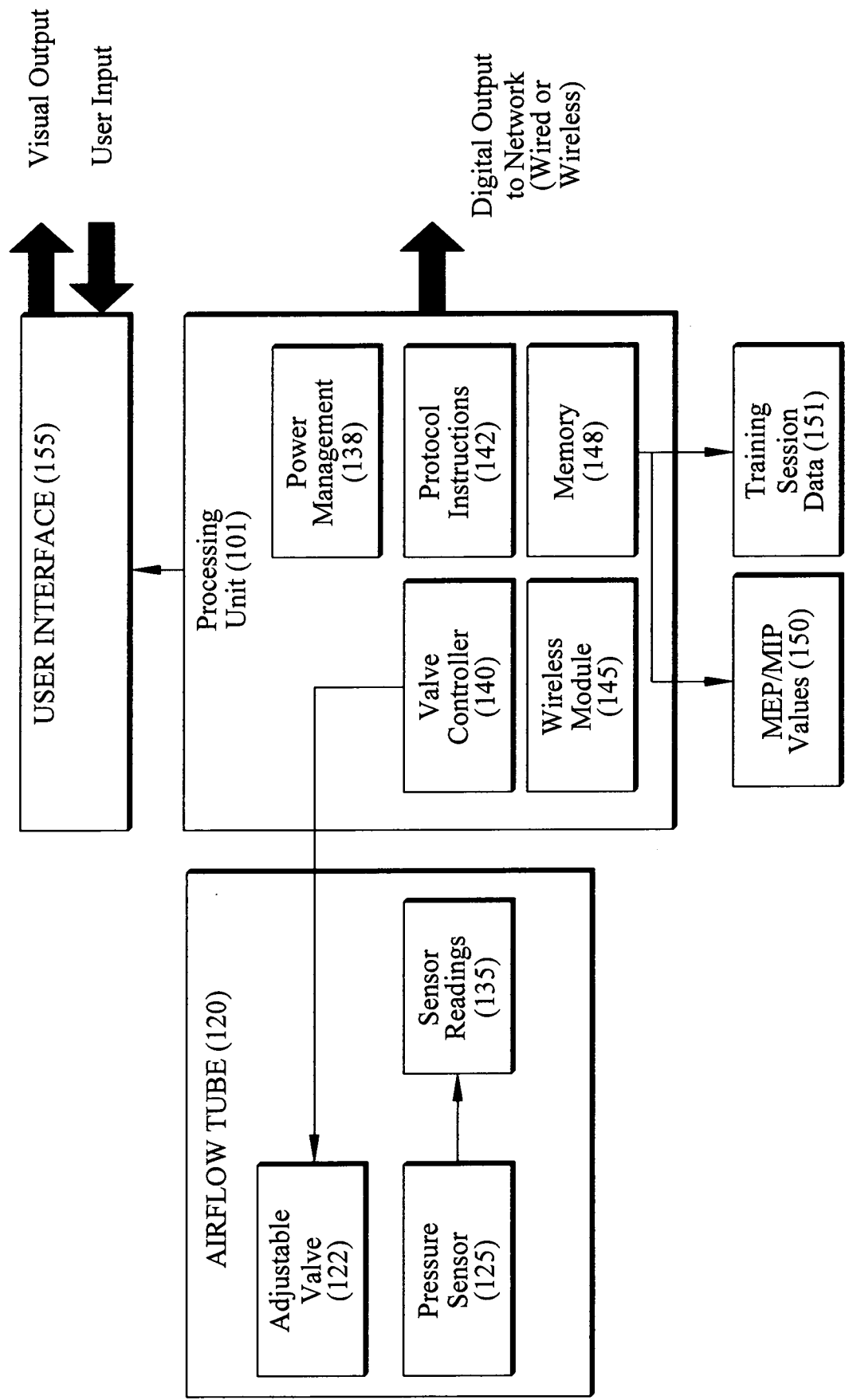


Figure 10

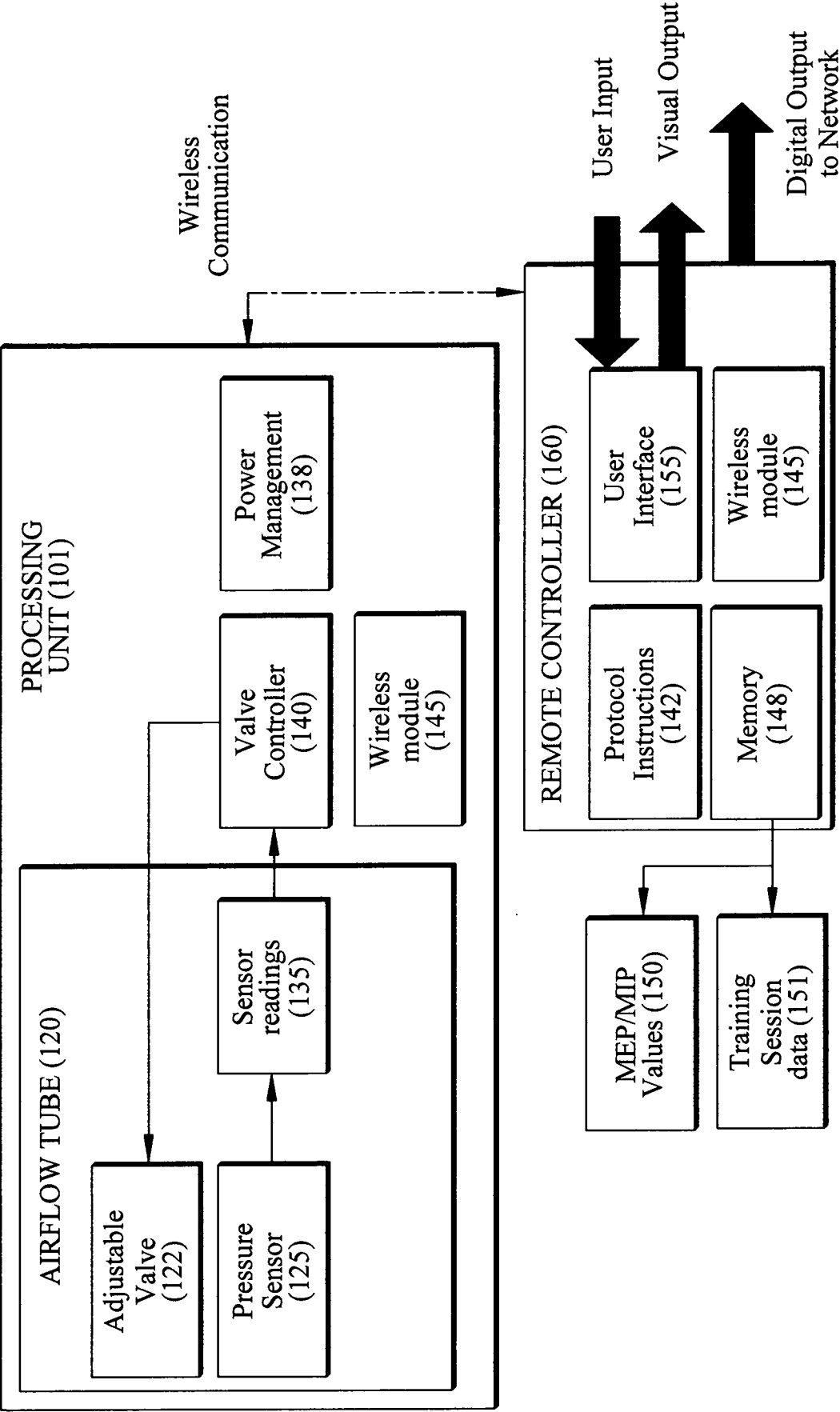


Figure 11

12/23

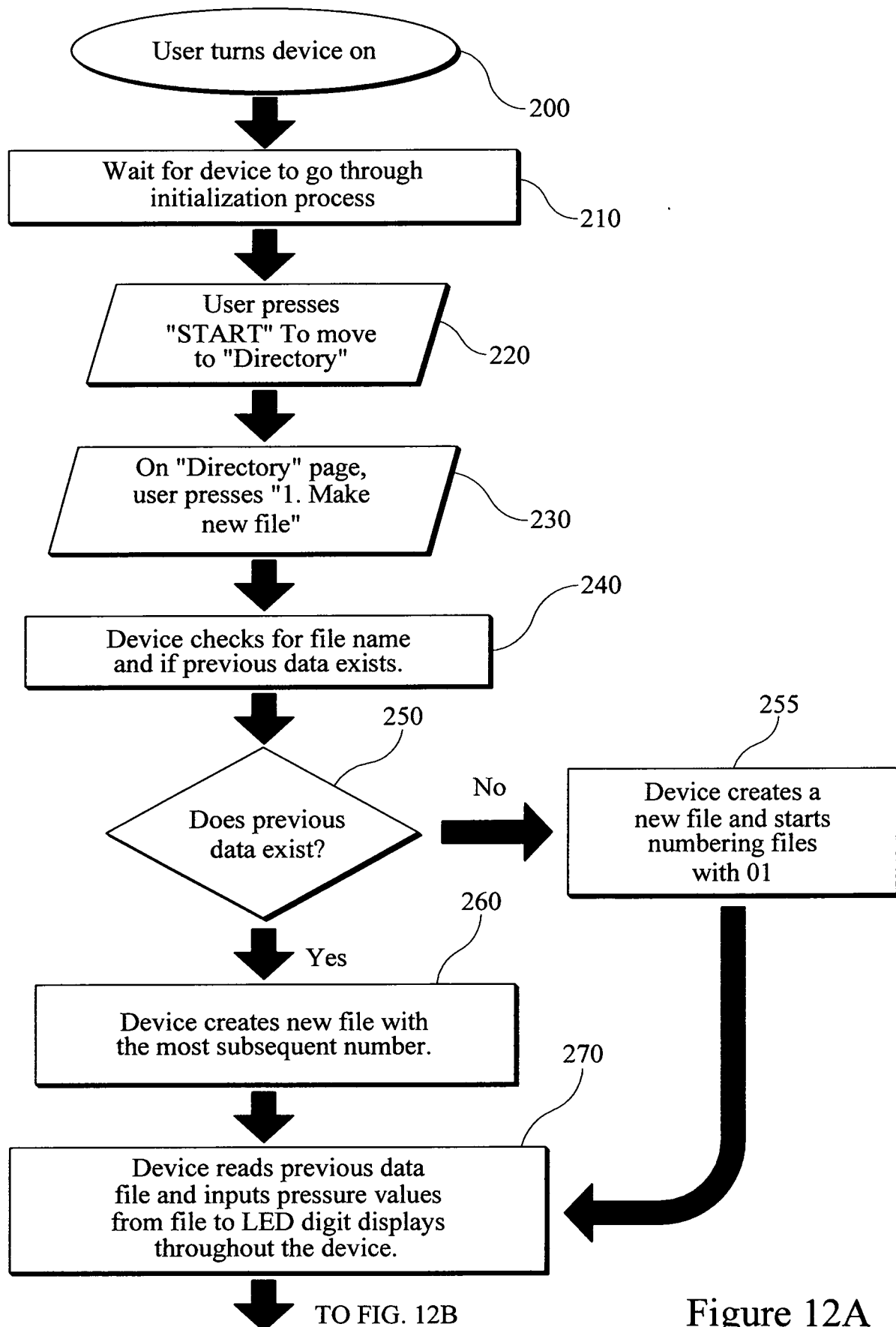
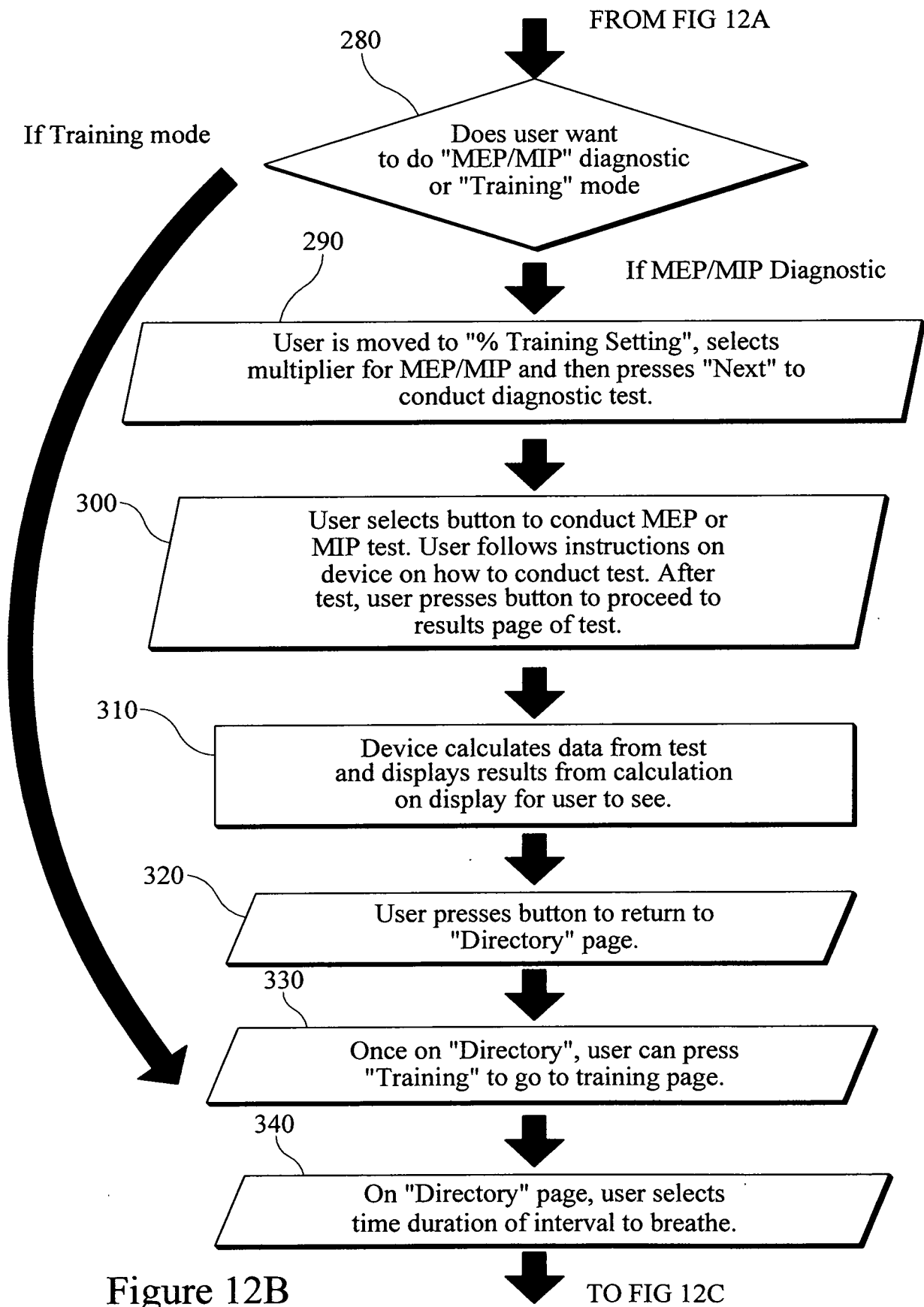
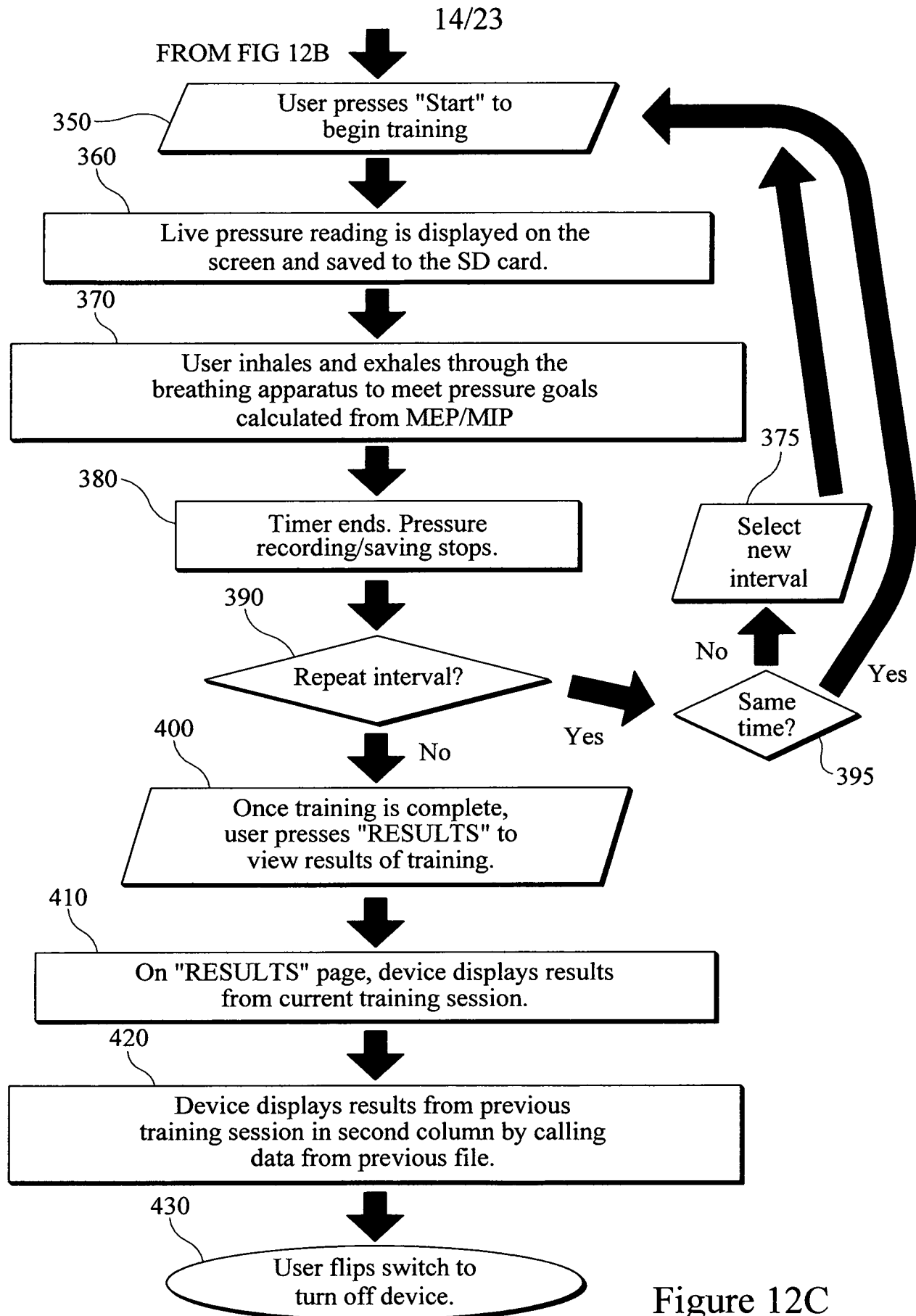


Figure 12A

13/23





15/23

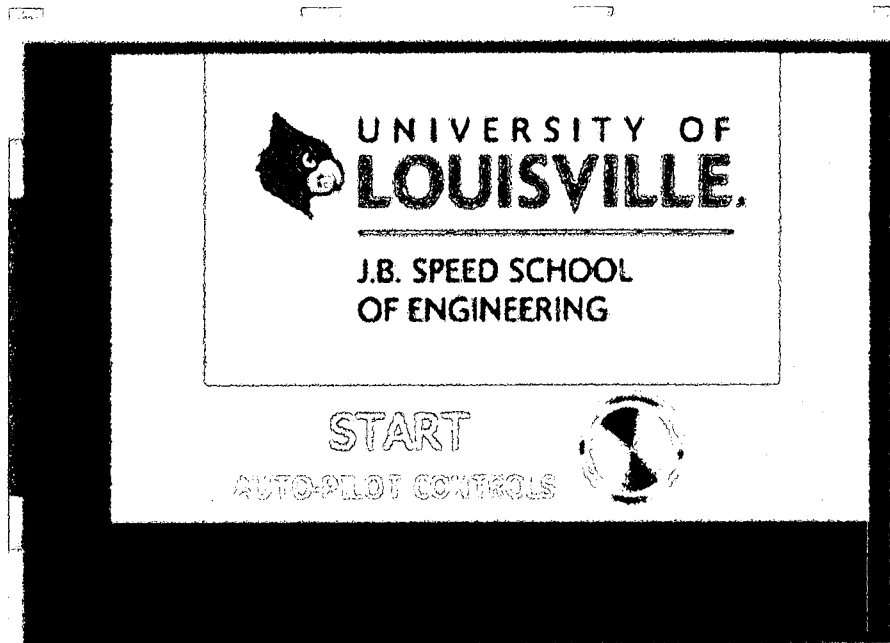


Figure 13

16/23

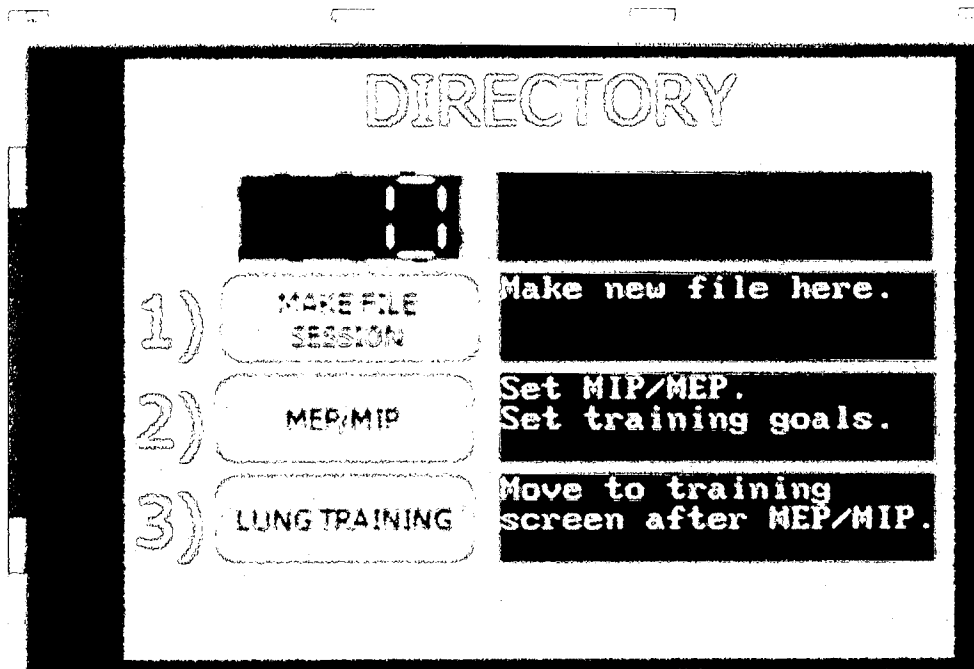


Figure 14

17/23

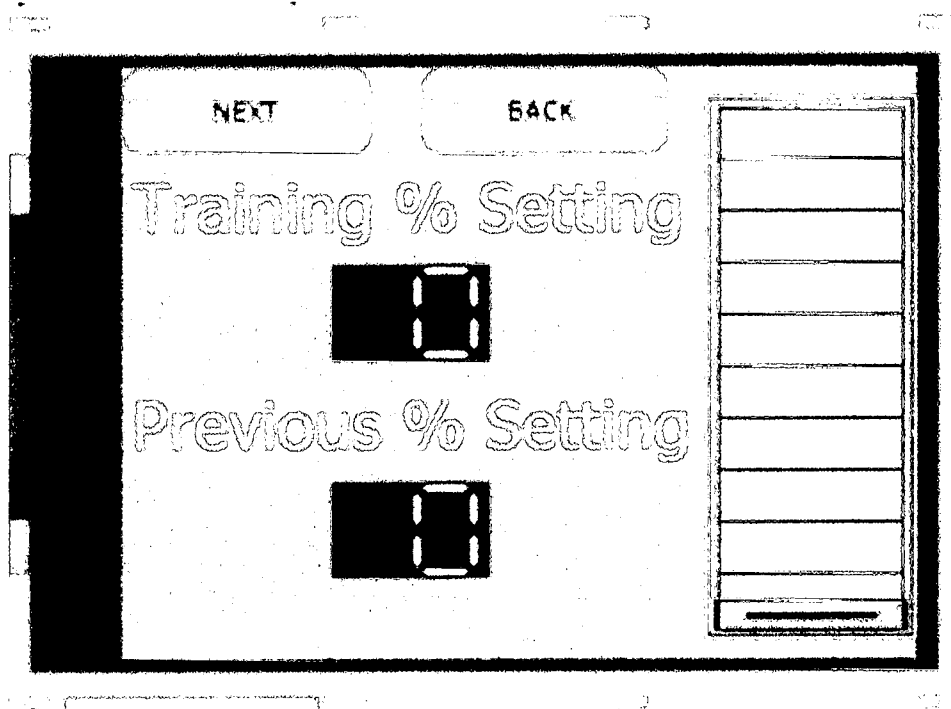


Figure 15

18/23

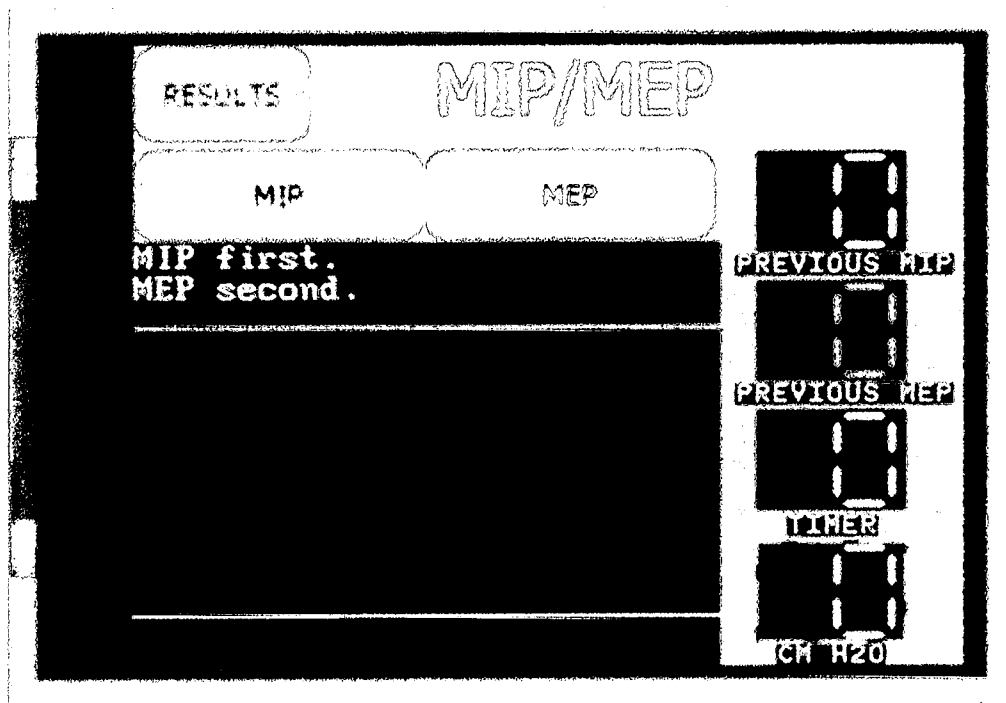


Figure 16

19/23

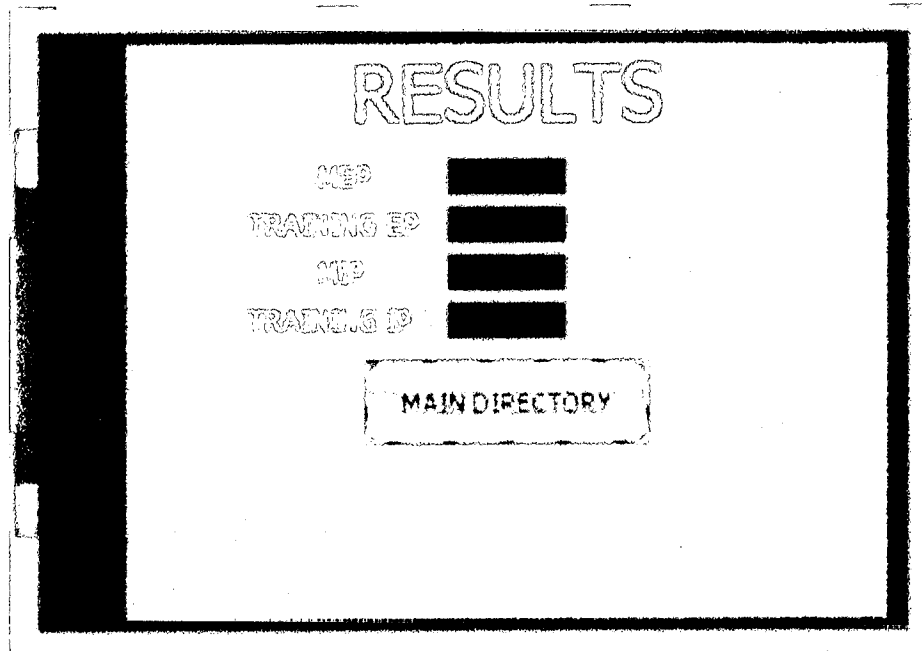


Figure 17

20/23

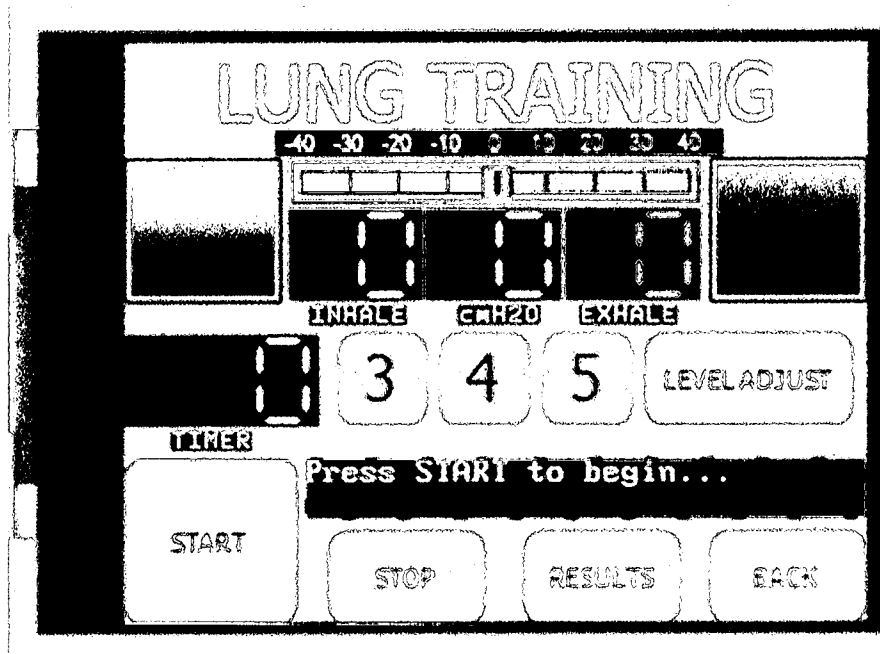


Figure 18

21/23

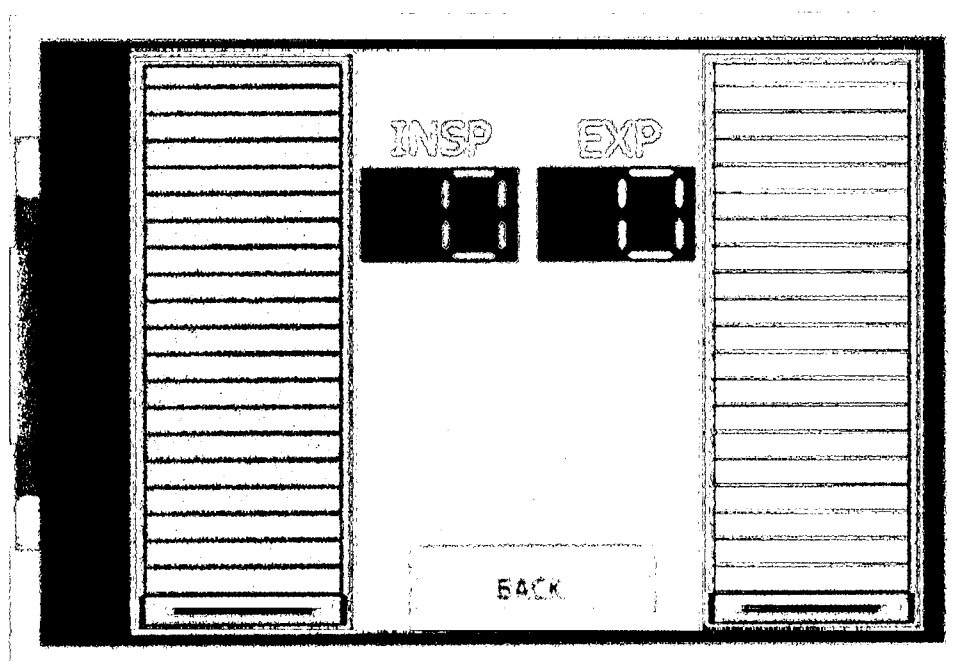


Figure 19

22/23

SESSION RESULTS		BACK
	TODAY	PREVIOUS
FILE NAME		
DATE (D/M/Y)		
TIME (H:M:S)		
HIGHEST EX.		
LOWEST IN.		
REP		
RIP		
TRAINING %		

SEE YOU NEXT TIME

Figure 20

23/23

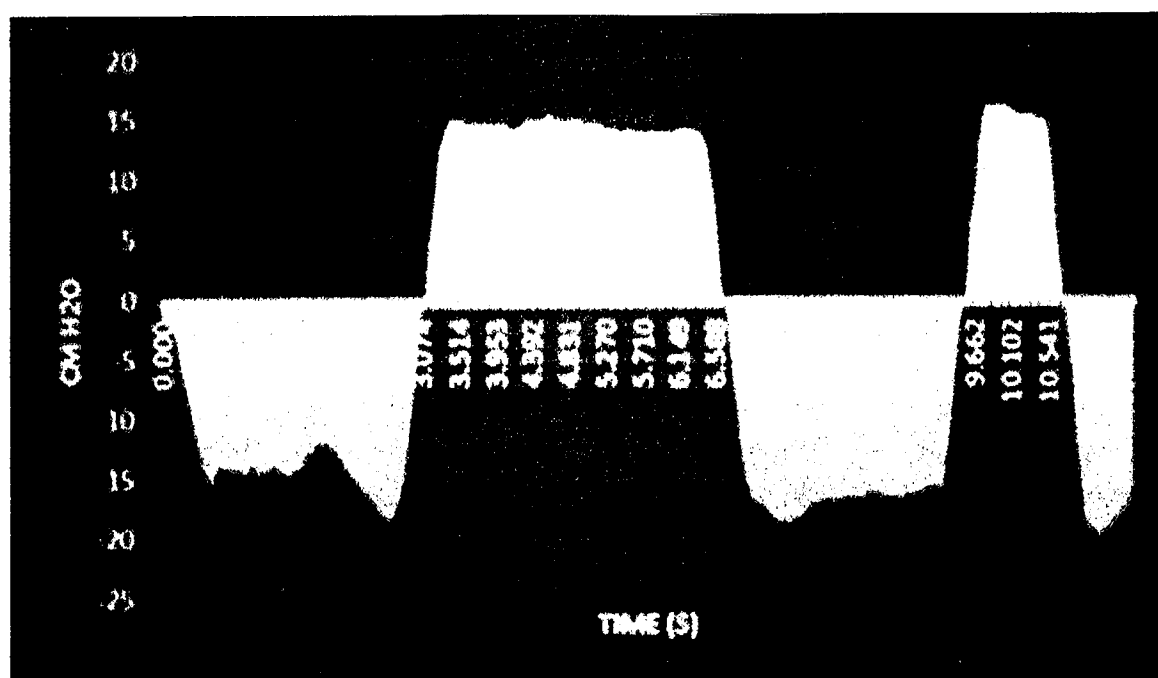


Figure 21

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2019/018024

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A63B 23/18; A61B 5/08; A61M 16/20; A63B 21/00; A63B 23/00 (2019.01)

CPC - A63B 23/18; A61B 5/08; A61M 16/20; A63B 21/00; A63B 23/00 (2019.02)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

USPC - 128/202.16; 128/207.16; 482/13; 601/41 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,533,137 A (SONNE) 06 August 1985 (06.08.1985) entire document	1-9, 11-15
Y	WO 2011/048244 A1 (DOLADE GUARDIA) 28 April 2011 (28.04.2011) see machine translation	1-9, 11-15
Y	US 2017/0020439 A1 (CHATHAM et al) 26 January 2017 (26.01.2017) entire document	1-9, 11-15
Y	US 5,255,687 A (MCKENNA) 26 October 1993 (26.10.1993) entire document	2, 15

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

24 April 2019

Date of mailing of the international search report

13 MAY 2019

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774