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(54) **PULMONARY SYSTEM RESISTANCE TRAINING APPARATUS AND METHODS**

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(57) **ABSTRACT**

A respiratory exerciser having a hollow body, where the hollow portion is in communication with a porous or non-porous material and with an opening that provides access for a user to breathe through the device.

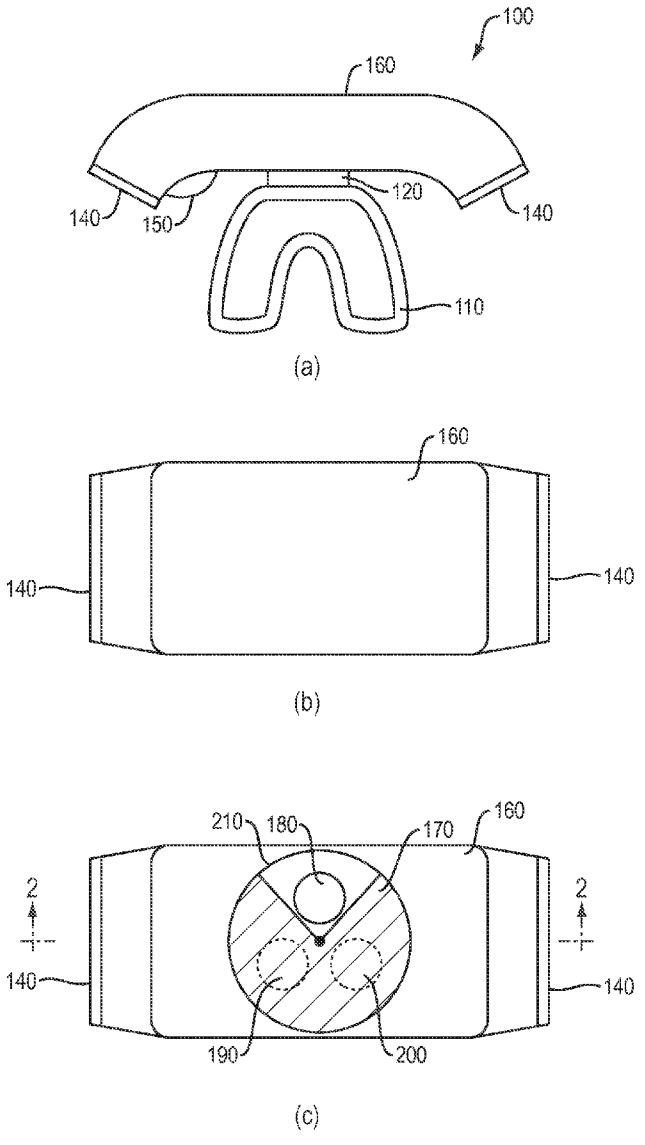
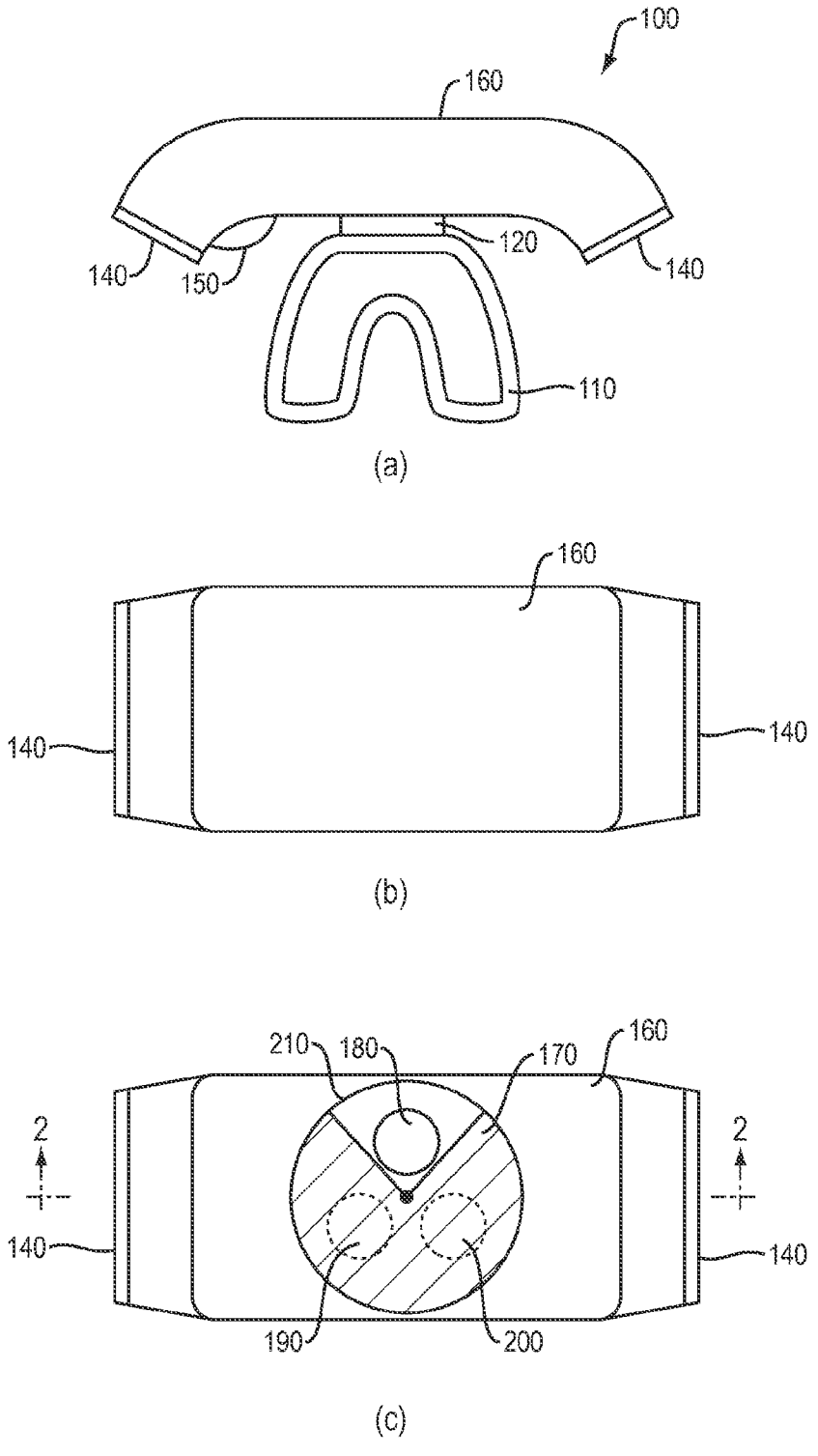


FIG. 1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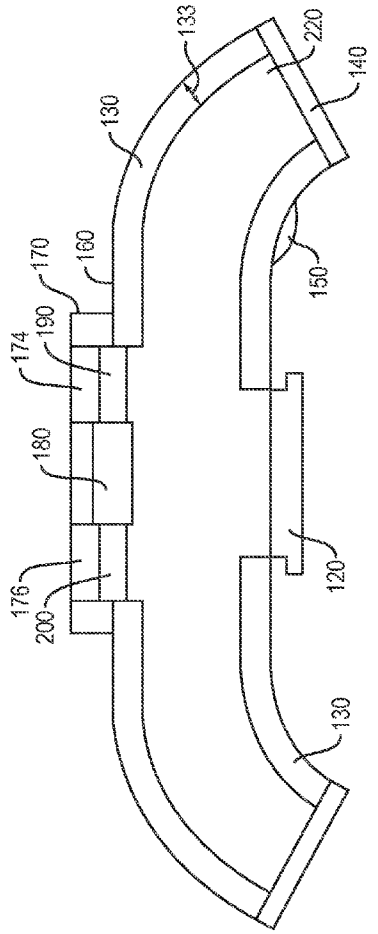
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FIG. 2

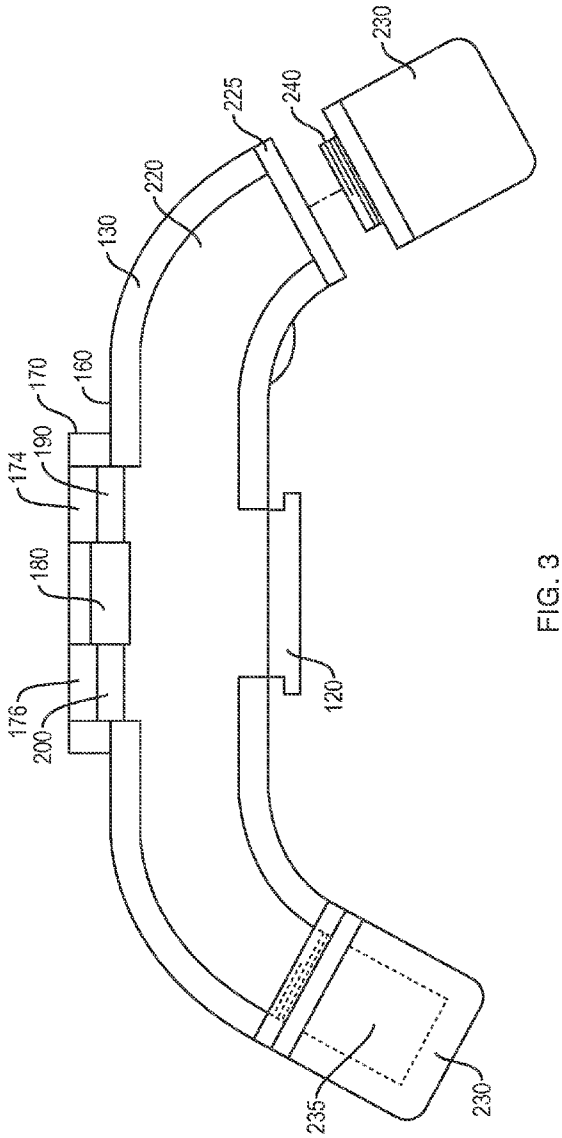
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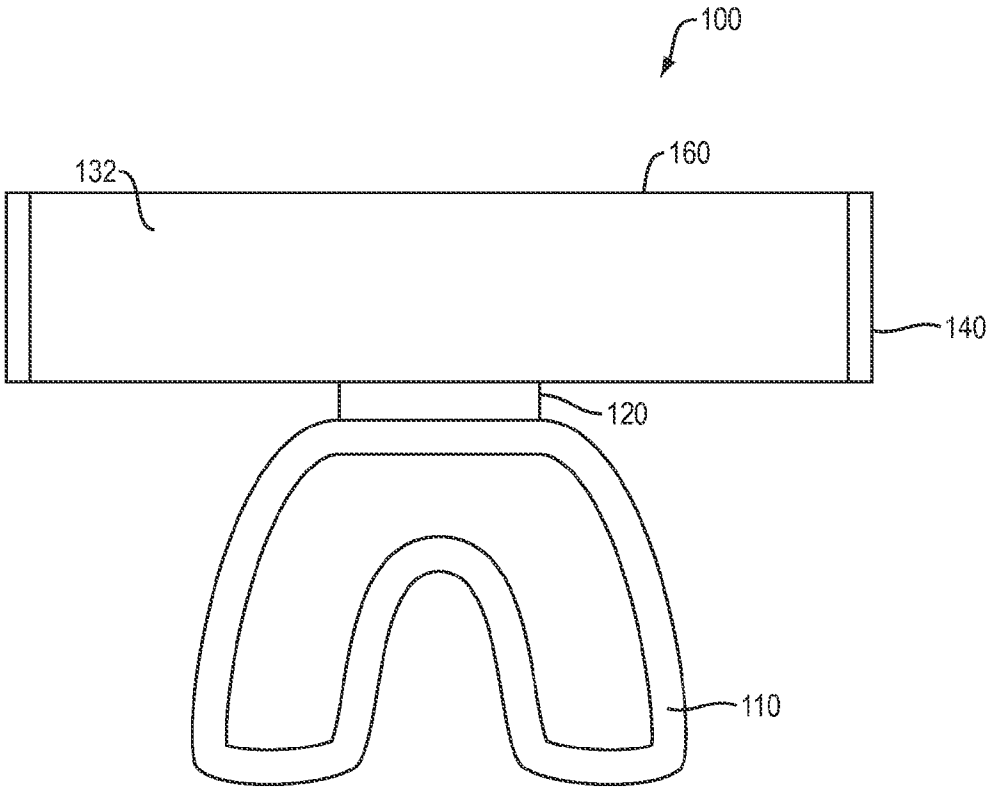
FIG. 3



(a)

FIG. 4

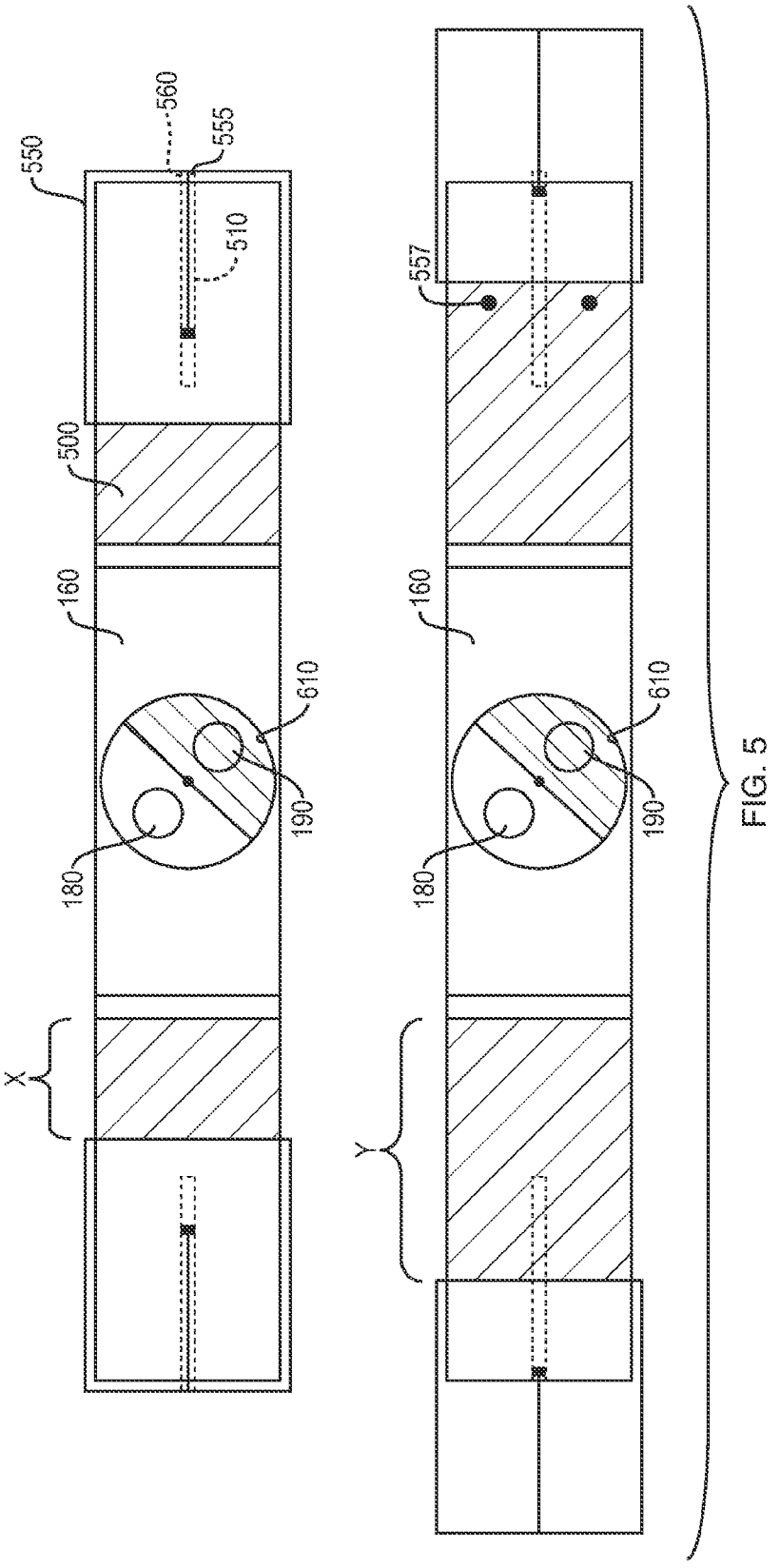


FIG. 5

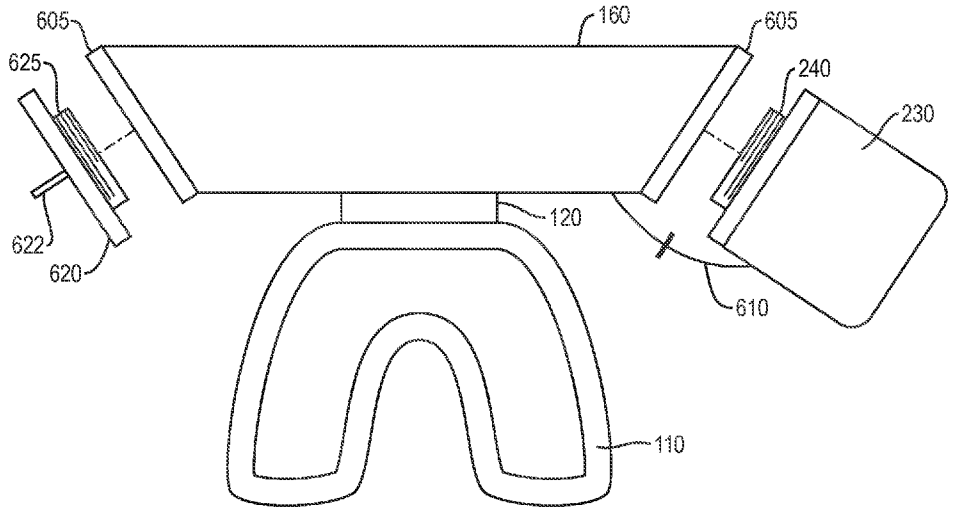


FIG. 6

PULMONARY SYSTEM RESISTANCE TRAINING APPARATUS AND METHODS

BACKGROUND OF THE INVENTION

[0001] Respiratory exercisers, in general, are designed for purposes including the assistance of patients with lung problems due to chronic obstructive pulmonary disease (COPD) or postoperative loss of spontaneous deep breaths. The types of devices vary-one type may provide inhalation resistance while a second type may provide exhalation resistance. The devices are designed so that resistance can be varied to adjust for the changing strength or weakness of the user.

[0002] Other respiratory exercise devices include large and/or complex multi-component assemblies of springs, valves, diaphragms notches and/or apertures, such as the devices shown in U.S. Pat. Nos. 6,726,598, 5,899,832 and 4,739,987, the contents of which are incorporated by reference in their entirety.

[0003] Other devices show exhalation through a porous component, as shown in U.S. Pat. No. 7,921,964 and WO 2009/106062, the entire contents of which are hereby incorporated by reference in their entirety. However, in these other devices, exhalation effort and pressure is sought to be minimized, and inhalation through the porous plastic is not possible due to valve restrictions to avoid drowning.

SUMMARY OF THE INVENTION

[0004] A pulmonary exercise device including a rigid body which can be formed from a non-porous material or at least partially from a porous material (e.g., porous plastic), having an interior space and a mouthpiece communicating with the interior space. In some embodiments, ambient air external to the rigid body can pass through the porous material into the interior space and then communicate with the mouthpiece during an inhalation event. In some embodiments, such inhaled gas communication can occur without one or both of: (1) communication through a non-adjustable one way valve or (2) by virtue of an external high pressure air or oxygen source urging gas flow into a user's lungs.

[0005] In another embodiment, a method of increasing pulmonary strength of a user includes the steps of obtaining a porous plastic pulmonary exerciser composed up at least (a) a rigid body having an interior passageway, (b) a mouthpiece communicating with the interior passageway, and (c) at least one porous plastic portion; and inhaling through the mouthpiece such that the inhalation urges a portion of air through the porous plastic portion, thereby increasing inhalation effort, wherein ambient air and the mouthpiece are in communication through the porous plastic member.

[0006] In another embodiment, a pulmonary exercise device includes a rigid body formed at least partially from porous plastic and having an interior space; and a mouthpiece communicating with the interior space, wherein air inhaled from a user during an exhalation event can communicate with ambient air external to the rigid body without communicating with a valve, wherein the user experiences a resistance of greater than 26 inches of water at an inhalation rate of 1 liter per second.

[0007] In one embodiment, the present invention includes a device body adapted to removably receive: (a) a one-direction valve having a cracking pressure of less than 1 psi; (b) a mouthpiece; and, (c) at least one other component selected from a cassette, a valve and a dead space introducing member.

[0008] A pulmonary exercise device comprising: a rigid device body formed at least partially from porous plastic having a porosity between 5 microns and 250 microns and a wall thickness of between 0.05 inches and 0.5 inches, wherein the rigid device body is adapted to removably receive: (a) a mouthpiece; and, (b) at least one other component selected from: (1) a cassette having a porosity between 5 microns and 250 microns and a wall thickness of between 0.05 inches and 1 inch, wherein the porosity or wall thickness of the cassette is different than the porosity or wall thickness of the device body, (2) a valve having a cracking pressure of less than 1 psi, and (3) a dead space introducing member.

[0009] Additional methods of use and other embodiments are also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Further details are explained below with the help of the examples illustrated in the accompanying drawings in which:

[0011] FIG. **1** shows various perspective view of embodiments of the present invention;

[0012] FIG. **2** shows a cutaway view along line A-A of FIG. **1**(*c*);

[0013] FIG. **3** shows an alternative embodiment using reference line A-A of FIG. **1**(*c*);

[0014] FIG. **4** shows a cutaway view of an embodiment of the present invention;

[0015] FIG. **5** shows an adjustable embodiment of the present invention; and

[0016] FIG. **6** shows an ergonomic embodiment of the present.

DETAILED DESCRIPTION OF THE INVENTION

[0017] The present invention relates to respiratory exercise devices and, more particularly, to breathing exercise devices which promote proper or stronger inhalation and exhalation by the user.

[0018] As with other resistance training, inhalation and exhalation resistance training can increase athletic performance. In certain instances, performance can be increased between 1 and 10 percent, most typically between about 2 and about 7 percent with about 5 percent not being an uncommon increase in physiologic/athletic performance. In certain embodiments, the present invention can be configured to provide one or more of flow resistance loading, pressure threshold loading or isocapnic hyperpnea. In certain embodiments, the present invention can be configured to provide one of flow resistance loading, pressure threshold loading or isocapnic hyperpnea and optionally provide an additional mode of operation (e.g., flow resistance and optionally pressure threshold and/or isocapnic hyperpnea). In one embodiment, the present invention can be configured to provide two or more of: flow resistance loading, pressure threshold loading or isocapnic hyperpnea.

[0019] In certain embodiments, the present invention includes a device body. The device body can be non-porous or include a porous portion, as a whole or as part of a device body. The present invention, in certain other embodiments optionally includes one or more of an optional cassette, an optional valve and an optional dead space introducing member.

[0020] In certain embodiments, a respiratory exercise device of the present invention includes a rigid or semi-rigid

body, where the body defines an interior space or hollow portion, and a mouthpiece in gaseous communication with the interior space, where ambient air external to the body can pass through a porous material into the interior space and then communicate with the mouthpiece during an inhalation event. Alternatively exhaled air can pass from a user into the interior space and then communicate with ambient air external to the present invention after passing through a porous portion of material. In certain embodiments, during an inhalation event some or a portion of ambient air can communicate with a mouthpiece without first opening or passing through a one way valve. In other embodiments, some or a portion of exhaled air can communicate with ambient air without first opening or passing through a one way valve.

[0021] As used herein, the general term "device of the present invention" or "present invention" is understood to include each of the device body, cassette, valve, or dead space introducing member alone or in any combination, as dictated by context and description.

[0022] In another embodiment, the present invention includes a pulmonary exercise device including a device body shaped to define an interior space, a mouthpiece boss, a one way valve cooperative with the rigid body and communicating with the interior space, permitting communication in a direction from the interior space to ambient air outside the rigid body, an aperture in communication with the interior space that freely permits a flow of air into the interior space from ambient air and also from the interior space to ambient air, a selector that is adapted to close at least either the one way valve or aperture, a porous plastic member cooperative with the rigid body and permitting communication between the interior space and ambient air, a mouthpiece connected to the mouthpiece boss and communicating with said interior space, wherein ambient air and the mouthpiece are in communication through the porous plastic member without communicating through a valve.

[0023] In certain embodiments, the present invention includes a generally linear device body or in certain embodiments a W-shaped, U-shaped, T-shaped or L-shaped body, in connection with a mouthpiece. None, all, or a portion of the overall device body may be composed of a porous material, e.g., porous ceramic, porous metal or porous plastic material. In certain embodiments, the weight of the present invention is sufficiently low so as to permit a user of the present invention to hold the present invention in the user's mouth solely by use of a mouthpiece. In such embodiments, the weight of the present invention can minimize jaw fatigue while the user is biting down on the mouthpiece and using the present invention, and also permits hands free use, e.g., during running, cycling, stair climbs, or other exercises involving cardiovascular or muscle training

[0024] Porous portions of the present invention (e.g., all or portions of the device body and/or cassette, and/or valve and/or a dead space introducing member) include pores or interconnected cavities permitting gaseous or fluidic communication throughout the solid porous portions. These pores allow ambient air to be in communication with the interior space of the present invention and thusly ambient air is in communication with a mouthpiece and by virtue of the mouthpiece, the lungs of a user. Unlike apertures, the porous portions create numerous (e.g., thousands of) indirect paths for air to travel through the material. By controlling the porosity and wall thickness of portions of the present invention a smaller, lighter, easier to clean, ergonomically shaped, and overall more simplified breathing resistance device can be created for use.

[0025] If the device body is non-porous or has a portion of porous material, then in such embodiments one or more additional porous cassettes can be connected to the device body to create an additional porous barrier between ambient air and a user. If all or a substantial portion of the device body is porous, the cassettes can also still be used and connected to the device body.

[0026] With respect to a porous portion, the porosity and wall thickness affect the resistance experienced by a user. Each is hereafter described.

[0027] Porosity

[0028] As described herein, portions of the present invention (e.g., the device body or cassette) can have varying porosity. The porosity of a portion of present invention, as defined by a standard porossimeter test, can be between 5 and 200 microns. In certain embodiments, the porosity can be between 5 and 100 microns. In certain embodiments, the porosity can be between 5 and 80 microns. In certain embodiments, the porosity can be between 5 and 50 microns. In certain embodiments, the porosity can be between 5 and 25 microns. In certain embodiments, the porosity can be between 10 and 50 microns. In certain embodiments, the porosity can be between 25 and 100 microns. In certain embodiments, the porosity can be between 25 and 200 microns. In certain embodiments, the porosity can be between 50 and 150 microns. In certain embodiments, the porosity is between 25 and 250 microns

[0029] In certain embodiments, the porosity of a porous portion, if any, of a device body or cassette or valve (e.g., a pressure threshold member) or dead space introducing member is selected from: about 5 microns, about 10 microns, about 20 microns, about 30 microns, about 40 microns, about 50 microns, about 60 microns, about 70 microns, about 80 microns, about 90 microns, about 100 microns, about 110 microns, about 120 microns, about 130 microns, about 140 microns, about 150 microns, about 160 microns about 170 microns, about 180 microns, about 190 microns, about 200 microns, about 210 microns, about 220 microns, about 230 microns, about 240 microns, about 250 microns, about 260 microns, about 270 microns, about 280 microns, about 290 microns, about 300 microns.

[0030] In certain embodiments, the porosity is less than 300 microns.

[0031] In certain embodiments, the porosity is less than 200 microns.

[0032] In certain embodiments, the porosity is less than 100 microns.

[0033] In certain embodiments the porosity is less than 75 microns.

[0034] In certain embodiments, the porosity is between 5 microns and 75 microns.

[0035] In certain embodiments, the porosity is between 5 microns and 250 microns.

[0036] Material Thickness

[0037] In certain embodiments, the thickness of the material that defines a portion of the device (e.g., the device body or cassette) can be between about 0.1 inches and about 2.0 inches. In porous embodiments, the thickness of the porous material is between about 0.1 inches and about 1.0 inches. In certain embodiments, the wall thickness is between about 0.05 and about 0.15 inches. In certain embodiments, the

thickness of the porous material is about 0.1 inches. In certain embodiments, the thickness of the porous material is about 0.2 inches. In certain embodiments, the thickness of the porous material is about 0.3 inches. In certain embodiments, the thickness of the porous material is about 0.4 inches. In certain embodiments, the thickness of the porous material is about 0.5 inches. In certain embodiments, the thickness of the porous material is about 0.6 inches. In certain embodiments, the thickness is between 0.1 and 0.6 inches. In certain embodiments, the thickness is between about 0.1 and about 0.15 inches. In certain embodiments, the thickness is between about 0.05 and 0.2 inches. In certain embodiments, the thickness is between about 0.05 and 0.5 inches. In certain embodiments, the thickness is between about 0.05 and 1 inch.

[0038] The porous material used in the present invention restricts airflow to provide inhalation resistance, exhalation resistance, or both.

[0039] In certain light weight and/or easy to clean embodiments, all or a portion of the present invention can be made from porous plastic. In certain embodiments, polyethylene (PE) ultra-high molecular weight polyethylene (UHMWPE), high-density polyethylene (HDPE), polypropylene (PP), polytetrafluoroethylene (PTFE), and polyvinylidene fluoride (PVDF) are suitable. Ethylene vinyl acetate (EVA), polyethersulfone (PES), polyurethane (PU) and PE/PP co-polymer are also suitable. The material, or a portion thereof, can hydrophobic or hydrophilic. Porous plastic material can be readily obtained from Genpore, 136 Morgantown Rd., Reading, Pa. 19607.

[0040] Inhalation and Exhalation Effort

[0041] In certain embodiments, the porosity and wall thickness of the present invention can be varied to provide the following loads experienced by a user during inhalation, exhalation or both. The inhalation effort, exhalation effort, or both, applies to use of the device body alone as well as use of a device body combined with one or more cassettes and/or pressure threshold members (e.g., a fixed or adjustable one way valve).

[0042] Respiratory loads can be classified as light, medium and heavy resistance and apply to both flow resistance loading and pressure threshold loading. To the extent there is overlap in ranges, such overlap in characterization may relate to the perceptions of the individual user.

[0043] In certain embodiments, the resistance is between 26 and 300 cm. water at a rate (inhalation or exhalation) of 1 liter per second. In certain embodiments the resistance is greater than or equal to 26 cm. water at 1 liter per second. However, in certain embodiments, inhalation resistance can be less, and in some embodiments, inhalation or exhalation resistance is from 10 to 25 cm. water at 1 liter per second.

[0044] Light resistance can be between 26 and 110 cm. water at 1 liter per second. In certain embodiments the resistance is about 35 cm. water at 1 liter per second. In certain embodiments the resistance is about 45 cm. water at 1 liter per second. In certain embodiments the resistance is about 56 cm. water at 1 liter per second. In certain embodiments the resistance is about 65 cm. water at 1 liter per second. In certain embodiments the resistance is about 75 cm. water at 1 liter per second. In certain embodiments the resistance is about 90 cm. water at 1 liter per second.

[0045] Medium resistance can be between 26 and 190 cm. water at 1 liter per second. In certain embodiments, resistance can be between 56 and 180 cm. water at 1 liter per second. In certain embodiments the resistance is greater than or equal to about 56 cm. water at 1 liter per second. In certain embodiments the resistance is about 70 cm. water at 1 liter per second. In certain embodiments the resistance is about 100 cm. water at 1 liter per second. In certain embodiments the resistance is about 140 cm. water at 1 liter per second. In certain embodiments the resistance is about 160 cm. water at 1 liter per second. In certain embodiments the resistance is about 170 cm. water at 1 liter per second. In certain embodiments the resistance is about 180 cm. water at 1 liter per second.

[0046] Heavy resistance can be between 30 and 300 cm. water at 1 liter per second. In certain embodiments, heavy resistance can be between 150 and 270 cm. water at 1 liter per second. In certain embodiments the resistance is about 150 cm. water at 1 liter per second. In certain embodiments the resistance is about 200 cm. water at 1 liter per second. In certain embodiments the resistance is about 230 cm. water at 1 liter per second. In certain embodiments the resistance is about 250 cm. water at 1 liter per second. In certain embodiments the resistance is about 270 cm. water at 1 liter per second.

[0047] In some embodiments, the resistance is greater than 56 cm. water at 1 liter per second. In some embodiments, the resistance is between 56 cm. water and 300 cm water at 1 liter per second.

[0048] In some embodiments, one or more of the device body, cassette or valve can impart a vibration or oscillatory effect on inhalation, exhalation or both. In some embodiments, the vibration is between 6 to 12 Hz. In some embodiments, the vibration is between 20 and 40 Hz. In other embodiments the vibration is greater than 20 Hz. In some embodiments, the vibration is about 5, 6, 7, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 24, 25, 30, 35 Hz.

[0049] Each of the device body, cassette, valve and dead space introducing member for isocapnic hyperpnea is hereafter described.

[0050] Device Body

[0051] The device body of the overall device of the present invention typically defines an interior (e.g., hollow) space through which exhaled and inhaled air can pass from external ambient air to a user, typically through a mouthpiece.

[0052] In certain embodiments, the body of the device that defines an interior space can be made from any material, such as plastic or metal. In some embodiments, the entirety of the body can be solid, non porous material (e.g., plastic).

[0053] However, in other embodiments, at least a portion of the device body is made from porous material, such as ceramic or porous plastic. In certain porous embodiments, an interior space is not required for the present invention to function. In certain porous embodiments, the entirety of the device body can be porous material with no clearly defined interior hollow space.

[0054] In certain embodiments, at least 10% of the overall weight of the device body, exclusive of any valves, mouthpieces, mouthpiece bosses, fittings, plugs or cassettes, is derived from porous material. In other embodiments, at least 20% by weight is porous material. In other embodiments, at least 30% by weight is porous material. In other embodiments, at least 40% by weight is porous material. In other embodiments, at least 50% by weight is porous material. In other embodiments, at least 60% by weight is porous material. In other embodiments, at least 70% by weight is porous material. In other embodiments, at least 80% by weight is porous material. In other embodiments, at least 90% by

weight is porous material. In other embodiments, at least 95% by weight is porous material. In other embodiments, the device body, is entirely porous.

[0055] In certain embodiments, the device body (e.g., free of any cassettes, dead space introducing members, mouthpiece, etc) is light weight and weighs less than 5 ounces. In certain embodiments, the device body weighs less than 4.5 ounces. In certain embodiments, the device body weighs less than 4.0 ounces. In certain embodiments, the device body weighs less than 3.5 ounces. In certain embodiments, the device body weighs less than 3.0 ounces. In certain embodiments, the device body weighs between 1.0 and 4.0 ounces. In certain embodiments, the device body weighs between 1.0 and 3.0 ounces.

[0056] In certain embodiments, when in use the center of gravity of the device (as determined when a device body is free of any cassettes or other components, or as determined inclusive of one or more of a valve, cassette, mouthpiece, dead space introducing member, etc), is located proximal to the lips of a user. In certain embodiments, the center of gravity is less than 1 cm. from the external surface of a user's lips. In certain embodiments the center of gravity is less than 1.5 cm away from a user's lip. In certain embodiments, the center of gravity is less than 2 cm away from a user's lips. In certain embodiments the center of gravity is less than 3 cm away from a user's lips. In certain configurations, the center of gravity is located in front of a user's lips. It is contemplated that in certain configurations the center of gravity of the device of the present invention can be located such that it is inside a user's mouth, proximal to the teeth (e.g., inside the oral cavity). In certain embodiments, it is contemplated that the center of gravity of the device of the present invention is proximal to, or in relative contact with, the lips or mouth of a user.

[0057] In certain embodiments, the present invention can be modular. In certain embodiments, the present invention includes a device body that is adapted to removably receive a breathing related component, e.g., a cassette, a valve (non-adjustable or adjustable) or a dead space introducing member. In certain embodiments, the present invention includes a device body that is adapted to removably receive at least two breathing components selected from: cassette, a valve (non-adjustable or adjustable) or a dead space introducing member. In certain embodiments where two or more breathing components are used in the present invention, the breathing components can be of the same type (e.g., two cassettes) or different types (e.g., a valve and a cassette).

[0058] Cassettes

[0059] In certain embodiments, the cassettes can alter, increase or reduce the inhalation or exhalation effort of a user of a device of the present invention while using a device of the present invention.

[0060] In certain embodiments, one, two or three or more cassettes having any regular or irregular shape can be used with the device body. In certain embodiments, a cassette can be generally cylindrical or tubular. In certain embodiments, a cassette can further define an interior (e.g., hollow) space such that the interior space of a cassette is in direct communication with an interior space of a device body.

[0061] A cassette (or other component for use in the present invention) can be placed in fluid (where fluid is understood to encompass gases or liquids) communication with the interior space of a device body by removable or permanent means such as threaded couplings, snap fittings, adhesives, heat application and the like. Such attachment methods may be integral, or of one piece construction, with the material or may be adhered to the material though the use of adhesive or sonic welding and the like.

[0062] As noted above, a cassette for use in the present invention can have the same or different porosity, wall thickness, or material composition as the device body. The differences in these factors as between the device body and cassettes allows for customization of the inhalation and exhalation effort to suit the needs of a particular user without the need for springs, diaphragms or valves.

[0063] In some embodiments where the device body includes a porous portion, the porosity of the cassette, wall thickness of the cassette, or both, can be different than the device body. In certain embodiments, the resistance to airflow through the device body is relatively high (e.g. about 270 cm. water or more) as compared to the resistance of a cassette. In such embodiments, use of cassettes can reduce the overall resistance to inhalation or exhalation airflow by providing paths of less resistance in communication with the mouthpiece and ambient air. Thus, inhalation effort and/or exhalation effort of a device of the present invention can be adjusted by varying the porosity and/or wall thickness of cassettes that are in communication with a device body and/or in communication with an interior space of a device body.

[0064] Any of the resistances described above can apply to a cassette. In addition, in certain embodiments where the device body includes a porous portion, the resistance to airflow in a cassette is 5% less than the device body when a device body is properly used alone. In other embodiments, the resistance is about 10% less than the device body. In other embodiments, the resistance is about 20% less than the device body. In other embodiments, the resistance is about 30% less than the device body. In other embodiments, the resistance is 40% less than the device body. In other embodiments, the resistance is about 50% less than the device body. In other embodiments, the resistance is 60% less than the device body. In other embodiments, the resistance is about 70% less than the device body. In other embodiments, the resistance is about 80% less than the device body resistance.

[0065] In other embodiments, the resistance of a cassette is 5% to 30% less than the device body. In other embodiments, the resistance is 5% to 80% less than the device body. In other embodiments, the resistance is 10% to 50% less than the device body.

[0066] In certain embodiments, a cassette of the present invention can include a one way valve (e.g., an adjustable one way valve, as described herein) and may optionally be free or substantially free of porous material.

[0067] In certain embodiments, a cassette can be used to create a modular device. In certain such embodiments, one or more cassettes can be stacked, coupled together or arranged in series (e.g., linearly), or in certain designs of a device body (e.g., a T-shaped design) one or more cassettes can alternatively be arranged in a parallel fashion relative to the device body. In other embodiments, one or more cassettes can simultaneously be arranged in both series and also in parallel.

[0068] Relative to a user, during inhalation a first porous cassette may be located in series (e.g., upstream) with a second porous cassette having the same or different inhalation resistance. Alternatively, a one way valve cassette (e.g., an adjustable one way valve) may be placed upstream or downstream (e.g., proximally or distally) relative to another cassette of any type.

[0069] In certain embodiments, a cassette for use in the present invention has a weight between 0.1 and 1 ounce. In certain embodiments, a cassette weighs less than 0.9 ounces. In certain embodiments, a cassette weighs less than 0.8 ounces. In certain embodiments, a cassette weighs less than 0.7 ounces. In certain embodiments, a cassette weighs less than 0.6 ounces. In certain embodiments, a cassette weighs less than 0.5 ounces. In certain embodiments, a cassette weighs less than 0.4 ounces. In certain embodiments, a cassette weighs less than 0.3 ounces. In certain embodiments, a cassette weighs less than 0.2 ounces.

[0070] In certain embodiments of the present invention, a cassette can have an opening on the distal end that can be optionally opened or closed by a user. The opening can be adapted to receive additional components (e.g., a one way valve) to be placed in series with the cassette (e.g., by virtue of a threaded or unplug-able opening).

[0071] The resistance to exhalation can also be increased or decreased by altering the exposure of the total amount of pores to ambient air, porosity, wall thickness, etc. In certain embodiments, an adjustable cap or other covering can be used to reduce or increase the amount of porous material that is exposed.

[0072] Alternatively, in some embodiments a device of the present invention can include one or more apertures in the device body or cassettes which can be covered or uncovered to increase or decrease resistance, respectively.

[0073] Valve

[0074] In certain embodiments, one, two or three or more one way valves can be used to affect the functionality of a device of the present invention by altering, facilitating or easing inhalation effort, exhalation effort or both. In another embodiment, a valve, such as a one way valve (e.g., adjustable or non-adjustable reed or flap type one way valve), a hole or aperture can be included to affect the functionality of the device such that a user can effectively turn off or significantly reduce (by at least 50 to 100%) or substantially eliminate the inhalation or exhalation resistance caused by the device. A one way valve can be integral with the device body or may be connected using connection types apparent to one of skill in the art upon reading this disclosure (e.g., a threaded fit, bayonet fit or adhesive fit). In one embodiment, a one way valve (e.g., an adjustable one way valve) can be removably coupled to a device body and/or substituted for, or used in series or in parallel with, a porous material cassette of the present invention.

[0075] One way valves can be used to select whether inhalation or exhalation of a user undergoes any appreciable resistance, depending upon the orientation of the valve relative to flow of fluid (e.g., air) through the valve. When oriented in a first position, the valve permits inhalation but prevents or substantially impedes exhalation flow through the valve. In a reverse of the first position, when oriented in a second position, the valve permits exhalation but prevents or substantially impedes inhalation flow through the valve. One way valves can also be used to impart threshold resistance loading, in that a threshold load must be exceeded before the valve will open, and the threshold must be maintained in order for the valve to remain open. One way valves can be used alone or in combination with a porous material.

[0076] For example a one way valve (adjustable or non-adjustable) can be used and oriented to allow for the rapid release of exhaled air from a user through a valve in the device body and into ambient air. However, upon inhalation the one way valve closes, thus forcing inhalation effort to increase as the inhaled air passes through a cassette, porous portion or other component of the device. In some embodiments, cracking pressures for valves, including non-adjustable valves can be less than: 1.0 psi, 0.3 psi, 0.2 psi, 0.15 psi, or 0.09 psi. In certain embodiments, the cracking pressure is less than 0.17 psi. In certain embodiments, the cracking pressure can be the initial cracking pressure necessary for an adjustable one way valve.

[0077] In other embodiments, the one way valve can be adjusted so that the valve itself, in addition to a porous portion of the device (e.g., the device body or cassette), provides for variability in resistance by virtue of compression springs, membranes, and the like. Such embodiments provide a resistance (i.e., a respiratory load) and any of the resistances described above with respect to the device body can be used with a valve of the present invention. In certain embodiments, the device body has a resistance to flow that is greater than the resistance to flow of the valve.

[0078] Examples of one way valves, adjustable one way valves, or membranes and the arrangement thereof can be found at U.S. Pat. No. 6,726,598 and U.S. Pat. No. 4,739,987, the entire contents of which are hereby incorporated by reference.

[0079] In certain embodiments, the housing of a one way valve can be constructed from a porous material as described herein.

[0080] In certain embodiments, a valve for use in the present invention has a weight between 0.1 and 1 ounce. In certain embodiments, a valve weighs less than 0.9 ounces. In certain embodiments, a valve weighs less than 0.8 ounces. In certain embodiments, a valve weighs less than 0.7 ounces. In certain embodiments, a valve weighs less than 0.6 ounces. In certain embodiments, a valve weighs less than 0.5 ounces. In certain embodiments, a valve weighs less than 0.4 ounces. In certain embodiments, a valve weighs less than 0.3 ounces. In certain embodiments, a valve weighs less than 0.2 ounces.

[0081] In certain embodiments, a valve can have an opening on the distal end that can be optionally opened or closed by a user (e.g., by using a threaded plug or the like). The opening can be adapted to receive additional components (e.g., a cassette) to be placed in series with the valve (e.g., by virtue of a threaded or unplug-able opening).

[0082] Dead Space Introducing Member for Isocapnic Hyperpnea

[0083] The average total lung capacity of an adult human male is about 6 liters and females it is about 4.2 liters. Functional residual capacity is the amount of air left in the lungs after normal exhalation. Men leave about 2400 ml on average while women retain around 1800 ml. Thus, men typically exhale 3.6 liters and women typically exhale 2.4 liters. Residual volume is the amount of air left in the lungs after a forced exhalation. The average residual volume in men is 1200 ml and for women is 1100 ml. Vital capacity is the maximum amount of air that can be exhaled after a maximum inhalation, where men tend to average 4800 ml and women 3100 ml.

[0084] In certain embodiments, the present invention the device body, alone or in combination with one or more of a cassette or adjustable or non-adjustable valve member, provides or is sufficient to provide a dead space volume. In certain embodiments, in the absence of a dead space introducing member, the volume of the device, alone or in com-

bination with one or more of a cassette or valve member, is insufficient to provide substantial retention/accumulation of carbon dioxide.

[0085] In certain other embodiments, in the absence of a dead space introducing member, the volume of the device, alone or in combination with one or more of a cassette or valve member, is sufficient to provide substantial retention/accumulation of carbon dioxide. Thus, in such embodiments, the device body and/or cassette and/or adjustable or non-adjustable valve member function as a dead space forming member.

[0086] In other embodiments, the present invention includes a member that introduces a dead space volume, where the dead space introducing member can, in some embodiments, be removably coupled to the device body (e.g. it is a modular component), or the member can be permanently affixed to the device body and/or arranged in parallel or in series with one or more of a cassette or valve as disclosed herein. The dead space introducing member can be any regular or irregular shape, and in certain embodiments it can be tubular. In certain embodiments, the dead space retaining member can be an expandable or elastomeric bag.

[0087] The dead space introducing member can be of any material having any parameters as described herein, (e.g., porous or non-porous). The purpose of the dead space volume and/or dead space introducing member is to retain a certain percentage of exhaled gas in the overall internal volume of the device, thereby maintaining an elevated level of carbon dioxide in the device of the present invention with each subsequent inhalation and/or exhalation. Such retention of carbon dioxide can reduce the incidence of hyperventilation.

[0088] In certain embodiments, excluding the amount of exhaled gas that may be present in the porous walls of the device, alone or in combination with one or more of a cassette or adjustable valve member, or dead space introducing member if a porous material is used in the manufacture of the dead space introducing member, the overall dead space is about 2%, 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55% of a typical exhalation volume of a user. In another embodiment, a dead space introducing member alone is sufficient to retain (or increases the overall volume of the total device) about 2%, 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55% of a typical exhalation volume of a user. Thus, in certain embodiments, the dead space introducing member is about 1.08 liters (i.e., 3.6 liters×30%) in volume.

[0089] Additional information concerning CO2 measurement can be found in U.S. Pat. No. 4,601,465 and WO2007/089465, the contents of which are incorporated herein by reference in their entirety.

[0090] Methods of Use and Treatment

[0091] The present invention can be used to treat or assist patients with breathing disorders, including patients having COPD, neuromuscular disease, quadriplegia, post operative complications resulting in altered lung function, dyspnea, chronic congestive heart failure and other related conditions.

[0092] The present invention can also be used to assist breath training in an athletic context to increase the strength and efficiency of breathing. In some embodiments, the resistance to inhalation, exhalation, or both, can be set such that a user can use an embodiment of the present invention for between 3 to 300 minutes per day. In some embodiments, a user can use the present invention periodically or continuously throughout an entire day. In some embodiments, a user can use the present invention for 10 to 20 minutes per day. In some embodiments, a user can use the present invention for more than 5 minutes per day. In some embodiments, a user can use the present invention for more than 20 minutes per day.

[0093] In some embodiments, the present invention can be used in a manner consistent with resistance training. In some embodiments, such resistance training includes a time period of exhalation and/or inhalation resistance or a predetermined number of breaths through a device of the present invention followed by a period of rest wherein the device of the present invention is not used. In some embodiments, the time period of breathing with resistance is selected from about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, about 30 seconds, about 45 seconds, about 60 seconds, 90 seconds, 120 seconds, about 10 seconds to 40 seconds, about 10 seconds to about 60 seconds, about 10 seconds to 90 seconds, about 10 seconds to 120 seconds.

[0094] In certain other embodiments, the predetermined number of breaths of a training set include at least 5, at least 10, at least 12, at least 15, at least 20, at least 25 at least 30, at least 40, between 5 and 15, between 10 and 20 breaths, between 20 and 40 breaths.

[0095] In other embodiments, the rest period is selected from about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, about 30 seconds, about 45 seconds, about 60 seconds, 90 seconds, 120 seconds, about 10 seconds to 40 seconds, about 10 seconds to about 60 seconds, about 10 seconds to 90 seconds, about 10 seconds to 120 seconds, about 6 hours, about 8 hours about 12, and between 8 and 12 hours. When used in a manner consistent with resistance training a user is typically not physically active (e.g., not running, biking, playing a sport or otherwise training, or in the alternative a user is sitting, driving or is generally not engaged in cardiovascular or muscular training during use of the device) and the user is focusing primarily on pulmonary exercise. The user can complete 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 sets with a rest period between each set. In some embodiments, a user can complete 3 or more sets, with a rest period between each set.

[0096] In certain embodiments, and as described below, the present invention is ergonomically formed, small enough and/or light enough that it can be used for or during endurance training or while exercising, e.g., while running, stair climbs, cycling, weightlifting, engaging in aerobics, walking, rock climbing, or swimming with a kickboard or other activity.

[0097] Alternatively, the device of the present invention can be used for much longer periods, e.g., for endurance training to impart or provide hill climb or high altitude training intensities. In such embodiments, the device of the present invention may be used while a user is relatively inactive (e.g., resistance training over an extended period) or while the user is actively covering/traversing a certain distance.

[0098] In one embodiment, a user may employ the present invention in the course of inhaling, exhaling, or both, for an extended period of time. In one embodiment, the device of the present invention may be used for about 3 minutes, about 4 minutes, about 5 minutes, about 10 minutes, about 15 minutes about 20 minutes. In some embodiments the present invention may be used for between 10 minutes and 60 minutes. In other embodiments a user can use the present invention for a time period greater than an hour.

[0099] In some endurance related embodiments, a user may actively traverse a distance while the user is also engaged in cardiovascular exercise, where the distance is selected from:

about 10 yards, about 100 yards, at least a quarter mile, at least a half mile, at least a mile, at least 3.1 miles, at least 6.2 miles at least 10 miles, at least 13.1 miles, at least 20 miles, at least 26.2 miles, at least 30 miles, at least 50 miles, from 1 mile to 10 miles, from about 3.1 miles to 13.1 miles from about 1 mile to 20 miles.

[0100] In some other embodiments, a user may actively undertake an elevation change while using the device. In such embodiments, a user may ascend at least: about 10 feet, about 20 feet, about 30 feet, about 50 feet, about 100 feet, about 500 feet, about 1000 feet, or about 5000 feet

[0101] In certain embodiments, the device of the present invention can be configured to provide flow resistive loading for inhalation and exhalation. In certain embodiments, the device of the present invention can be configured to provide flow resistive loading for inhalation only. In certain embodiments, the device of the present invention can be configured to provide flow resistive loading for exhalation only. In certain embodiments, the device of the present invention can be configured to provide pressure threshold loading for inhalation and exhalation. In certain embodiments, the device of the present invention can be configured to provide pressure threshold loading for inhalation only. In certain embodiments, the device of the present invention can be configured to provide pressure threshold loading for exhalation only. In certain embodiments, the device of the present invention can be configured to provide pressure threshold loading for inhalation and flow resistive loading for exhalation. In certain embodiments, the device of the present invention can be configured to provide flow resistive loading for inhalation and pressure threshold resistance for exhalation. Isocpanic hyperpnea (e.g., by using a dead space introducing member if the device of the present invention does not provide sufficient dead space already), can be used in combination with any of the forgoing configurations.

[0102] Other Components

[0103] In some embodiments, the present invention can include a nose clip and or nose clip holder to close the nose of user and thereby force a user to breathe solely through the user's mouth and therefore solely through the device of the present invention. The nose clip can be separate or integrated with the device of the present invention. Alternatively, the present invention can be used in combination with a nasal inspiratory resistance trainer such as that shown in U.S. Publication No. 20130157810, the contents of which are incorporated by reference.

[0104] In other embodiments, the present invention includes two raised nubs which function to plug the nose of a user. The raised nubs can be solid plastic, a soft material or porous plastic, or any other material suitable for at least partially blocking the nasal passageway of a user.

[0105] Other embodiments may also include packaging and instructions for using a device of the present invention, e.g., for a kit including the device.

[0106] Other embodiments may also include one, two or three or more clip portions or eyelets which permit the attachment of a necklace or string to a portion of a device of the present invention to permit a user to simply spit out the device of the present invention (or in case the device of the present invention falls out of a user's mouth during exercise) such that the present invention can hang around a user's neck, thereby permitting continued hands free operation and reducing the incidence of inadvertent loss of the device. Accordingly, in one embodiment, the present invention includes the method of a user releasing the device of the present invention (e.g., from the user's mouth) while still retaining possession of the device. In certain other embodiments, the necklace or string can include an elastomeric material so as to facilitate retention of the device of the present invention in a user's mouth. Specifically, the elastomeric material (e.g., rubber or elastic) provides tension support around a user's head. However, in certain embodiments, such support permits the easy removal of the device of the present invention from a user's mouth by one or more of spitting, by hand, or merely mouth relaxation (e.g., in the case of loss of consciousness).

[0107] In certain porous embodiments, the porous nature of the present invention may also permit additional constituents to be adhered to a porous portion. In such embodiments, detection of disease, e.g., liver disease, gastrointestinal disease, diabetes or cancer, can be accomplished by contacting a surface with appropriate detection agents such that disease biomarkers in saliva and exhaled air (e.g., nitric oxide, acetone, volatile organic compounds) can be detected (e.g., by a change in color) upon contact of the disease biomarker with the detection agents.

[0108] In certain other embodiments, the present invention includes a porous member alone or in combination with a flexible sheet (e.g., neoprene), to there by provide resistance. In such an embodiment one or more of the porous portions described herein can be integral with such a flexible sheet, such that the sheet forms a mask to be worn by a user, such that the mask forms at least a partial seal on a user's face to thereby cause the user to breathe through the porous member.

[0109] In certain embodiments, the present invention does not provide a seal for the nose, or is free of nose sealing, where should such sealing be necessary, such sealing can be provided by a secondary component, e.g., a nose clip.

[0110] In certain embodiments, the components of the device of the present invention (e.g., the device body or cassette) can be constructed free of adhesives. In some embodiments, the portions of the overall device of the present invention may be welded (e.g., sonically welded) together or friction fit together.

EMBODIMENTS

[0111] Referring to FIGS. **1** through **6**, there is illustrated various non-limiting embodiments of the present invention.

[0112] With respect to FIG. **1**, FIG. **1**(*a*) shows a top perspective view a device body **100** of one embodiment of a T-shape design of the present invention. FIG. **1**(*b*) shows a front view of device **100** with front portion **160**. Front portion **160** can optionally include a selector **170** to manually choose between an exhale only one way valve **180**, inhale only one way valve **200** and open aperture or valve **190**. Selector **170** can be of any design, including sliding or rotary, which in turn can be seated in rotary track **210**.

[0113] In addition, device **100** can also include a mouthpiece mating boss **120** and optionally removable mouthpiece **110**. Ends **140** may be a porous material, non-porous or an end cap, as detailed further in FIG. **6**. The angle **150** may be from 0 degrees to 90 degrees, with 15 to 25 or 30 to 55 degrees being preferred.

[0114] FIG. **2** shows a cutaway view along line A-A of FIG. **1**(*c*). The device body **130**, which may or may not also be porous, has a wall thickness **133** (which may be uniform or non-uniform thickness throughout the device **100**) and which defines an interior or hollow space **220**. Plugs **176** and **174** of

selector **170** seal the apertures or valves **200** and **190**, to thereby permit the exhale only valve one way valve **180** to function.

[0115] FIG. **3** shows an alternative embodiment along line A-A of FIG. **1**(*c*), where the ends **140** have been replaced with coupling elements **225**. In one embodiment, threads **240** threadingly engage coupling element **225** to couple porous cassette **230** to device **100**. In one embodiment, porous cassette **230** further includes interior portion **235**. When cassette **230** is coupled to device **100**, the interior portion **235** of the cassette is in communication with interior portion **220** of the device **100** body.

[0116] FIG. **4** shows a cutaway view of a porous device that is free of any interior or hollow portion. Rather, the entire device **100** is entirely composed of porous material.

[0117] FIG. **5** shows an adjustable embodiment of then invention. Caps **550** threadingly engage cassettes **500** via thread portion **510** and screw portion **555** in bore **560**. Alternatively, the outer portion of cassettes **500** can be threaded to allow for a threading connection of cal **550** to cassette **500**.

[0118] By adjusting the distance X that cap covers cassette **500**, the amount of exposed surface area can be increased or decreased, thereby increasing or decreasing the resistance to inhalation or exhalation felt by a user. For example, as the amount of exposed area increase to Y, the inhalation effort experienced by a user decreases. Exhalation effort is kept at a minimum by virtue of one way exhaust valve **180** which rotary selector **610** is exposing to ambient air while covering open aperture **190**.

[0119] In addition, apertures **557** may be present on portion of a device body **130** or cassette **500** or **210**. Apertures **210** can be covered or exposed by a user to alter further the effort of breathing experienced by the user.

[0120] FIG. **6** shows an alternative embodiment where ends **140** have been replaced with coupling elements **605**. Device **100** also has angled ends **120**. In one embodiment, threads **240** threadingly engage coupling element **225** to couple porous cassette **230** to device **100**. In one embodiment, other end **605** is coupled to a plug **620** having threads **625** which substantially match threads **240** of cassette **230**. Plug **620** can be tightened or loosened by any means, however as shown in FIG. **6**, tab **622** can be used to rotate plug clockwise or counterclockwise to thereby loosen or tighten plug **620**.

[0121] As used herein, the term "about" means + or −10% of the value referenced, inclusive of the value referenced. Thus "about 10" is understood to fully support both "10", as well as the range of "9 to 11" Moreover, the term "about" is understood to be optionally applicable to every value set forth herein, whether or not explicitly stated as such in this disclosure. Thus, for example, a value of "10%" set forth herein is understood to support a claim limitation of "10%" as well as a claim limitation of "about 10%."

[0122] It is also understood that individual values provided as part of a listing of values may be selected individually. For example, "2%, 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%" is understood to mean that any particular value may be selected from the list and used or claimed alone, e.g., 2% or 30%, 55% or about 55%).

[0123] In this disclosure, there is shown and described various embodiments of the invention. However, as aforementioned, the invention is capable of use in various other combinations and environments and is capable of changes or modifications within the scope of the inventive concept as expressed herein. Various embodiments may be altered or combined with other embodiments without changing or altering the scope of this disclosure.

[0124] Each and every reference set forth in this disclosure is hereby incorporated by reference in its entirety as if set forth fully herein.

1-20. (canceled)

21. A pulmonary exercise device comprising:

a rigid body formed at least partially from porous material and having an interior space; and,

a mouthpiece communicating with said interior space, wherein ambient air external to the rigid body can pass through the porous material into the interior space and then communicate with the mouthpiece during an inhalation event without flowing through a valve.

22. The device of claim **21**, wherein the porous material comprises porous plastic having a porosity of between about 5 microns and about 500 microns.

23. The device of claim **22**, wherein at least a portion of the porous plastic has a thickness of between 0.1 to 1.0 inches.

24. The device of claim **21**, wherein the rigid body is removably connected to a second rigid body.

25. The device of claim **21**, further comprising a one way valve in communication with said interior space.

26. The device of claim **23**, wherein the porosity and wall thickness are sufficient to create a resistance of 10 to 25 inches of water during a user's inhalation at a rate of 1 liter of air per second.

27. The device of claim **23**, wherein the porosity and wall thickness are sufficient to create a resistance of greater than 26 inches of water during a user's inhalation at a rate of 1 liter of air per second.

28. A method of increasing pulmonary strength comprising;

obtaining a porous plastic pulmonary exerciser comprising (a) a rigid body having an interior passageway, (b) a mouthpiece communicating with the interior passageway, and (c) at least one porous plastic portion;

inhaling through the mouthpiece such that the inhalation urges a portion of air through the porous plastic portion, thereby increasing inhalation effort, wherein ambient air and the mouthpiece are in communication through the porous plastic member.

29. The method of claim **28**, wherein at least a portion of the porous plastic has a porosity of between about 5 microns and about 500 microns.

30. The method of claim **28**, wherein at least a portion of the porous plastic has a thickness of between about 0.1 to 1.0 inches.

31. The method of claim **28**, wherein the exerciser further comprises a one way valve cooperative with the rigid body such that upon exhalation at least a portion of the exhaled air bypasses the porous plastic portion and exits the exerciser through the valve to thereby minimize an increase in exhalation effort.

32. The method of claim **28**, wherein the user traverses at least 100 yards while using the device hands free.

33. A pulmonary exercise device comprising:

a rigid body formed at least partially from porous plastic and having an interior space; and,

a mouthpiece communicating with said interior space, wherein air inhaled by a user during an inhalation event can communicate with ambient air external to the rigid body by traversing through the porous plastic and with-

out communicating through a valve, wherein the user experiences a resistance during the inhalation event.

34. The device of claim **33**, further comprising a one way valve cooperative with the rigid body wherein upon exhalation, at least a portion of the exhaled air bypasses the porous plastic portion and exits the pulmonary exercise device through the valve to thereby minimize an increase in exhalation effort.

35. The device of claim **33**, wherein the rigid body has a weight of less than 5 ounces.

36. The device of claim **33**, further comprising a cassette having a weight between 0.1 and 1 ounce.

37. The device of claim **33**, wherein the center of gravity of the device is located proximal to a user's teeth.

38. The device of claim **33**, further comprising a dead space introducing member.

39. The device of claim **33**, further comprising a cassette in fluid communication with the rigid body and a one way valve in fluid communication with the rigid body wherein upon exhalation, at least a portion of the exhaled exits the exerciser through the valve to thereby minimize an increase in exhalation effort.

40. The device of claim **33**, further comprising an adjustable one-way valve having a cracking pressure of less than 0.3 psi in fluid communication with the rigid body.

41. A pulmonary exercise device comprising: a device body and a rigid cassette formed at least partially from porous plastic having a porosity between 5 microns and 250 microns and a wall thickness of between 0.05 inches and 0.5 inches, wherein the rigid device body is adapted to removably receive: (a) a mouthpiece; and, (b) at least one other component selected from: (1) a valve having a cracking pressure of less than 1 psi, (2) a cassette having an aperture, (3) a cassette having a valve with an adjustable cracking pressure, and (4) a dead space introducing member.

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