Abstract: A therapeutic device for treating one or more conditions associated with a user's nasal cavities, sinuses, and/or ear canals. The therapeutic device includes a vibration generator configured to provide a vibration to a nasal interface located over a nose, around the nose or in the nose of the user. The therapeutic device further includes a gas module configured to provide a gas having a positive pressure to the user at a chamber and a seal configured to maintain the positive pressure at the chamber. The therapeutic device further includes a power module configured to provide power to the vibration generator to create the vibration and a housing which the user may hold and which is connected to the vibration generator, the gas module, and the power module.
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THERAPEUTIC DEVICE FOR TREATMENT OF CONDITIONS RELATING TO THE SINUSES, NASAL CAVITIES, EAR, NOSE AND THROAT

REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Patent Application No. 62/394,355 filed on September 14, 2016, the entire contents of the provisional application being incorporated herein by reference.

BACKGROUND

[0002] Many individuals suffer from sinusitis, which is characterized by upper airway mucosal edema, inflammation and obstruction. Normally, the sinuses are filled with air, but inflammation and edema cause obstructions, fluid (e.g., mucus, drainage, etc.) and/or infectious material (e.g., bacteria, viruses, etc.) to accumulate. Sinusitis causes many uncomfortable symptoms, including pain resulting from pressure in the sinus cavities, nasal mucus discharge, headaches, and many others. Accordingly, there is a need to treat sinusitis, including acute, subacute, recurrent and/or chronic sinusitis.

[0003] In addition, Eustachian equilibrium may be lost when a person encounters sudden changes in pressure, such as when an airplane takes off and/or lands, which causes the pressure in the ear canals to become unbalanced. There is a need to treat this loss of Eustachian equilibrium that results from sudden changes in pressure.

SUMMARY

[0004] According to an implementation, described herein, a therapeutic device for treating one or more conditions associated with a user's nasal cavities, sinuses, and/or ear canals, the therapeutic device may include a vibration generator configured to provide a vibration to a nasal interface of the user, the nasal interface located over a nose, around the nose or in the nose of the
The therapeutic device may also include a gas module configured to provide a gas having a positive pressure to the user at a chamber and a seal configured to maintain the positive pressure at the chamber. The therapeutic device may also include a power module configured to provide power to the vibration generator to create the vibration and a housing which the user may hold and which is connected to the vibration generator, the gas module, and the power module. The therapeutic device may further include a user interface mounted to the housing and operable by the user to control one or more of the following functions of the therapeutic device: increase the positive pressure of the gas; decrease the positive pressure of the gas; modulate the positive pressure of the gas; increase the frequency of the modulation of the positive pressure of the gas; decrease the frequency of the modulation of the positive pressure of the gas; turn on the positive pressure of the gas; turn off the positive pressure of the gas; increase the vibration produced by the vibration generator; or decrease the vibration produced by the vibration generator. The gas module of the therapeutic device may serve as the vibration generator by modulating the positive pressure of the gas. The therapeutic device may further include a medication module configured to provide a medication to the user and a user interface mounted to the housing and operable by the user to control one or more of the following functions of the therapeutic device: turn on the medication module to provide medication to the user; turn off the medication module to stop medication from being provided to the user; increase the amount of medication provided to the user via the medication module; or decrease the amount of medication provided to the user via the medication module. The therapeutic device may include a seal on the housing and a chamber located within the housing. The therapeutic device may further include a nasal pillow extending from the housing and connected to the vibration generator. The seal may be located on the nasal pillow, and the chamber may be located within the nostril associated with the nasal
pillow. The vibration may be delivered to the user via the nasal pillow, and the nasal pillow may further include ballast. The power module may provide power generated by the breath of the user or a crank operated by the user to the vibration generator to provide the vibration to the user. The power provided by the power module may be electrical power or rotational power.

The therapeutic device may further include at least one of a temperature control module to warm the gas or a humidity control module to increase or decrease the humidity of the gas. The gas may correspond to one or more of: air, oxygen, nitrogen, helium, carbon dioxide, water vapor, exhaled breath of the user, or helox. The positive pressure of the gas may be from four to twenty-five centimeters of water or from four to ten centimeters of water. The therapeutic device may include a valve that prevents the positive pressure in the chamber from exceeding a threshold.

According to another implementation, described herein, a manually operated therapeutic device for treating one or more conditions associated with a user's nasal cavities, sinuses, and/or ear canals, may include a vibration generator configured to provide a vibration to a nasal interface of the user, the nasal interface being located over a nose, around the nose or in the nose of the user. The therapeutic device may further include a power module configured to provide power generated by the user to the vibration generator and a gas module configured to provide a gas having a positive pressure to the user at a chamber. The gas module may include a reservoir that may be filled by the exhaled breath of the user to provide the positive pressure of the gas. The therapeutic device may further include a seal configured to maintain the positive pressure at the chamber and a housing that the user may hold and that is connected to the seal, the vibration generator, the power module and the gas module. The power generated by the user
may come from the exhaled breath of the user or a crank rotated by the user. The therapeutic device may include a cover.

[0006] According to another implementation, described herein, a method for treating one or more conditions associated with a user's nasal cavities, sinuses, and/or ear canals, may include providing a therapeutic device that includes a vibration generator configured to provide a vibration to a nasal pillow located at a nasal interface of the user, the nasal interface located in a nose of the user. The therapeutic device may further include a gas module configured to provide a gas having a positive pressure to the user at a chamber and a seal configured to maintain the positive pressure at the chamber. The method may further include operating the therapeutic device to provide the vibration to the nasal pillow and operating the therapeutic device to provide the gas to the chamber.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0007] Figure 1 represents an example environment in which the technology, described herein, may be implemented.

[0008] Figure 2 represents a non-limiting example embodiment of the therapeutic device of Figure 1.

[8009] Figure 3 depicts an alternative embodiment of the therapeutic device of Figs. 1 & 2.

**DETAILED DESCRIPTION**

[0010] The apparatus, systems, methods, technologies and/or techniques (hereinafter "technology") described herein may provide a therapeutic device for the treatment of sinus conditions as well as methods by which users use the therapeutic device to treat sinusitis, and various other ailments of the sinuses, nasal cavities, ear, nose, throat, etc. The technology may be described in Figs. 1-3. Figs. 1-3 are attached hereto and incorporated herein by reference. The
following detailed description refers to the accompanying Figs. 1-3. The same reference numbers in different figures may identify the same or similar elements. The embodiments depicted in Figs. 1-3 are example embodiments, but the present technology may be embodied in many different embodiments.

[0001] Figure 1 depicts a non-limiting example environment in which the technology described herein may be implemented. As shown in Fig. 1, environment 100 may include a user 110, who may apply a therapeutic device 120 to form a seal 130 at/around the nasal passages (covered by the therapeutic device 120 in Fig. 1) of the user. The user 110 may position the therapeutic device 120 by placing the therapeutic device 120 on, over, around or within the nostrils, nose, mouth, and/or lace of a user. The seal may form a chamber associated with the nasal passages of a user 110, which chamber may be substantially air-tight and/or water-tight. The seal 130 may maintain a pressure within a chamber, may prevent or limit an amount of gas from entering and/or escaping the therapeutic device into the environment and/or may ensure that the user inhales some or all of the gas/medication/etc. being provided by the therapeutic device (e.g. via the chamber). The user 110 may suffer from one or more sinus conditions (e.g. mucus, drainage, infection, inflammation, pressure imbalance in sinuses and/or ear canals, etc.) that may be treated by therapeutic device 120. The seal may be located in the nasal passages, outside of the nasal passages, on the face around the nasal passages (as shown in Figure 1), etc. The therapeutic device may include a gas module (which may further including temperature and humidity controls), a vibration generator, a power module, a medication module, a valve, nasal pillows, and/or ballast for the purpose of treating sinus conditions as further described herein. The components illustrated in Figure 1 are provided for explanatory purposes only, and the disclosure herein is not intended to be limited to the components provided therein. There may he
additional components, fewer components, different components, and/or differently arranged components that illustrated in Figure 1. Also, in some implementations, one or more of the components/modules of the therapeutic device of Figure 1 may perform one or more functions described as being performed by another one or more of the components/modules of the therapeutic device of Figure 1. Further, the therapeutic device 120 of Figure 1 is depicted as a device having a single-body construction. The therapeutic device may be formed as a single component and/or multiple components in a variety of structural designs and/or arrangements. Figure 1 depicts an example environment 100 in which the technology may be implemented. Sample embodiments employing the technology are further described below.

Figure 2 depicts an example embodiment of the therapeutic device 120 of Figure 1. As shown in Figure 2, therapeutic device 120 may include a housing 210 having a user interface 211, a valve 212, a seal 220, a vibration generator 230, nasal pillows 240, a gas module 250, a power source 260 and a medication module 270. The components illustrated in Figure 2 are provided for explanatory purposes only, and the disclosure herein is not intended to be limited to, or to require, the components provided therein. There may be additional components, fewer components, different components, and/or differently arranged components than illustrated in Figure 2. Also, in some implementations, one or more of the components/modules of the therapeutic device of Figure 2 may perform one or more functions described as being performed by another one or more of the components/modules of the therapeutic device of Figure 2. For example, and not limitation, the functions of vibration generator 230 may be provided by gas module 250 and/or power source 260.

The therapeutic device may include one or more modules that can impart a controlled amount of vibration to the user, via the nasal interface, in a manner that stimulates the nasal and
sinus cavities of the user and/or relieves conditions related to the sinuses, nasal cavities, ears, nose and/or throat. The therapeutic device may also, or alternatively, include one or more modules that may provide a gas to a user, via the nasal interface, in a manner that stimulates the nasal and sinus cavities of the user and/or relieves conditions related to the sinuses, nasal cavities, ears, nose and/or throat. The therapeutic device may also, or alternatively, include one or more modules to control the temperature and/or humidity level of the gas, and/or combine a controlled amount of medication (e.g., in liquid and/or powder form) with the gas. The therapeutic device may include a power module that stores power (e.g., a battery, battery pack, etc.) and/or receives power (e.g., a power supply that receives and/or controls power from an alternating current source), and/or can be manually powered by the user (e.g., by inhaling, exhaling, or some other means of manual power).

[0013] Housing 210 may be held by the user when using therapeutic device 120 to treat a sinus condition. Additionally, or alternatively, housing 210 may provide a chamber (e.g. when seal 220 is applied to the nasal interface) that may store a gas at a pressure and/or a medication to be delivered to a user to treat one or more of the conditions described herein. Additionally, or alternatively, one or more of the components of therapeutic device 120 may be permanently and/or removably mounted, installed and/or attached to housing 210 so that therapeutic device 120 may be more compact, convenient and/or be a one-piece design. Housing 210 may enclose one or more of the modules, discussed herein. Housing 210 may include a user interface 211 formed by one or more buttons, levers, displays, touch screens, dials, etc. with which the user may interact to control the therapeutic device (e.g. control vibration; control gas pressure, temperature, flow and/or humidity; medication delivery, etc.). The user interface 211 may include a power switch, one or more buttons or user interfaces to control the settings associated
with the modules described herein such as, for example, gas pressure, dosage, vibration level, vibration frequency, temperature, humidity, etc. The user interface may include a display, which may present information that identifies parameters associated with the modules described herein, such as charge level, gas level, pressure level, medication level, moisture level, vibration level, vibration frequency, temperature, etc.

[0014] Housing 210 may further include a valve 212, which may regulate the pressure and/or flow of gas into and/or from a chamber associated with housing 210. For example, and not limitation, valve 212 may correspond to a poppet valve, which may prevent the pressure within the chamber from exceeding a certain threshold associated with an opening pressure of the poppet valve. Additionally, or alternatively, valve 212 may correspond to a check valve, which may prevent a vacuum and/or pressure below ambient pressure from being created (e.g. when the user inhales) within chamber. Additionally, or alternatively, valve may correspond to a pressure regulation and/or flow regulation valve, which may limit the pressure within the chamber and/or the flow rate of a gas into and/or from the chamber.

[0015] Housing 210 may be formed from a material or materials of sufficient strength and rigidity (e.g. a polymer, a metal alloy, fiberglass, composite, etc.) to support the static and/or dynamic loads (e.g. forces, torques, tensions, compressions, stresses, strains, etc.) imparted on the housing 210 by the components of therapeutic device 120 (such as when they are installed on housing, apply pressure to housing, etc.), to support the handling of therapeutic device by the user, to support the pressures and/or vibrations imparted to the housing 120 by the user and/or the components of the therapeutic device 120.

[0016] Seal 220 may be separate component that is permanently and/or removably attached to housing 210, nasal pillows 240 and/or some other portion of therapeutic device 120 that may
create a **chamber** at the **Basal** interface of a user. A user may apply the seal 220 (e.g. by grasping housing and pressing seal around a nasal interface) to the user to form a chamber within which a gas (e.g., a **pressurized** gas, a therapeutic **gas**, etc), **medication**, humidity, etc. may reside prior to being inhaled by the user. Seal 220 may be completely and/or **partially**- air-tight. In the embodiment depicted in Figure 2, seal 220 is located on a surface of housing 210 that comes in contact with the face of the user. Additionally, or alternatively, seal 220 may be placed in other locations, such as nasal pillows 240. As depicted in Figure 1, seal 220 may be formed in a shape (e.g., a mask, cover, etc.) that can fit over or around the nose of the user and/or the nose and mouth of the user. In this example, seal 220 may enable a positive pressure (e.g. above ambient pressure) to be created, controlled and/or maintained within a **chamber** (e.g., volume inside of the housing 210, etc.) when a gas is provided to the user by the therapeutic device 120. As further discussed herein, the pressure may be constant, modulated, may cause a vibration, etc. Additionally, or alternatively, therapeutic device 120 may provide a treatment (e.g. **vibration**, humidity, medication, **temperature controlled gasses** and/or medications, etc.) from one or more of the modules to the user via seal 220.

**[0017]** Seal 220 may be formed from a material or materials of sufficient strength and **rigidity** (e.g. polymers, robbers, metals, etc.) to support the static and/or dynamic loads (e.g. forces, torques, tensions, compressions, stresses, strains, etc.) imparted on the seal by other components of therapeutic device 120. For example, and not limitation, seal 220 may support vibration loads associated with pressure variation and/or a vibration generation device, may support pressure loads associated with the application of a pressure to the user. Additionally or alternatively, seal 220 may be formed from a material or materials of sufficient flexibility and **resilience** to be compressed by a user (such as when forming a "seal at and/or around the nasal
interface) and/or to be comfortably used by the user. For example, seal 220 may be formed from a gasket-like material, which may be comfortable to the user and/or may maintain pressure within a chamber formed by the seal 220.

Vibration generator 230 may provide mechanical vibrations to the user via the nasal interface (e.g. at seal 220, nasal pillows 240, etc.). Vibration generator 230 may contain one or more mechanical vibration-generating components (e.g., offset weight devices, cam-driven devices, etc.). For example, vibration generator may include one or more electrically driven vibration components, including, but not limited to, an eccentric rotating mass motor, an offset weight motor, a linear resonant actuator, a piezoelectric bender, etc. Additionally, or alternatively, the vibration generator may be mechanically driven. For example, the user may power a vibration device by breathing into the nasal interface. By inhaling and/or exhaling, the user may rotate a set of blades (e.g., a rotor blade, turbine blade, fan blade, etc.) that may be attached to a shaft associated with a mass that is offset from the center of the shaft. As the shaft rotates, the offset weight is rotated which creates a centrifugal force that is applied to the user when, for instance, the shaft is connected to (e.g. the shaft is allowed to rotate in a bearing and transfer the vibration forces, etc.) the nasal interface (e.g. connected to a member associated with nasal pillows 240, seal 220, etc.) Additionally, or alternatively, the user may exhale to fill a reservoir (e.g. such as a reservoir located within gas module 250) with exhaled breath (e.g. through a check valve that allows exhaled air to enter but not escape, etc.), and the pressure created and/or stored within the reservoir may be used (e.g. when another valve is operated, such as controlled by user interface 211, to allow gas to escape the reservoir, etc.) to rotate the set of blades to rotate the shaft that generates the vibration. Additionally, or alternatively, the user may manually operate a shaft (e.g., by operating a crank, etc.) to create vibrations, such as in the ways.
described herein. The scope of the present disclosure is not limited to the foregoing examples of vibration generation. Any type of known vibration device may be used. For example, an internal mass may be attached to a spring that may be depressed by a shaft that rides along a cam, which may be connected to a shaft that is driven by the user (e.g., the user's breath, by hand, etc.). Transferring the vibrations to the user via a nasal interface may stimulate the nasal and/or sinus cavities in a manner that breaks up and/or loosens liquid, mucus, solids and/or an obstruction within the nasal and/or sinus cavities of the user. Such stimulation may promote drainage of the nasal and/or sinus cavities. Additionally, or alternatively, the vibrations may open the ear canal to relieve pressure from the ear drum, which may be created by an infection, mucus, and/or changes in pressure (e.g., taking off and/or landing in an airplane).

Nasal pillows 240 may be one or more members that fit within the nose of the user. Nasal pillows 240 may transfer vibrations to the user, such as vibrations generated by vibration generator 230, pressure module 250, etc. Additionally, or alternatively, nasal pillows 240 may form a seal (e.g. by including a seal, such as seal 220) in the nasal passages of a user to permit a treatment (e.g. a pressurized gas, medication, etc.) to be provided to the user in a chamber within the nose via nasal pillows 240. For instance, nasal pillows 240 may include one or more passageways (e.g. penetrations/tubes, etc.) (hot shown) through which medication, pressurized gas, etc. may be transferred from one of the modules, described herein, to the user.

Nasal pillows 240 may include one or more ballast components that are attached to, integrated into and/or formed as part of the nasal pillows. Additionally, or alternatively, ballast components may be attached to, integrated into, and/or formed as a part of another component of therapeutic device 120 associated with transferring vibrations to the user, such as seal 220 or housing 210. Ballast components may be formed by high density materials (e.g., steel, copper.)
lead, molybdenum, silver, gold, tungsten, platinum, high density polymers such as Bcomass®, high gravity compound ceramics, etc.). The high density materials may be ergonomically shaped to fit in, over, or around the nostrils, nose, mouth and/or face of the user. For example, and not limitation, the high density materials may form a seal (similar to seal 220 except at nasal pillows) within the nostrils of a user. The mass, inertia, and/or momentum of the ballast components may enable vibrations to be imparted to the user via the nasal interface (e.g. at the nasal pillows 240, at seal 220, housing 210, etc.). Ballast components may cause vibrations to be transferred to the user in a manner that causes the nasal and/or sinus cavities of the user to vibrate accordingly. Such vibration may stimulate the nasal and/or sinus cavities in a manner that causes the fluids, mucus, solids and/or other obstructions, within the nasal and/or sinus cavities, to be loosened, drained and/or otherwise removed from the nasal and/or sinus cavities. The vibrational forces provided to the user via ballast components as described above, may be generated by the vibration generator 230, by gas module 250 (e.g. modulated gas pressure may cause the nasal interface and/or the ballast components to vibrate in a manner that imparts the vibrational forces to the user) and/or by another component and/or module of therapeutic device 120 that may generate vibrations as described herein. Nasal pillows 240 may extend from housing 210 (e.g. be connected to housing and/or ballast components associated with housing, etc.), vibration generator 230, gas module 250 (such as when gas module 250 is formed as a part of housing 210, etc.), etc, to the nostrils of user when the user uses therapeutic device 120 as described herein.

Gas module 250 may provide a gas (e.g., air, water vapor, oxygen, nitrogen, helium, helox, carbon dioxide, or a combination of gases, etc.) to a user via the nasal interface (e.g. within a chamber formed by housing 210 and seal 220, within the nostrils via nasal pillows, etc.) at a positive pressure (e.g. above ambient pressure). Gas module 250 may provide gas at
different modes, such as a constant mode where a constant pressure is applied when a user inhales, exhales or both; a modulated pressure, where the pressure varies; upon request by the user, etc. Gas module 250 may be connected to (e.g. formed as a part of, via an airtight connection, etc.) housing 210, nasal pillows 240 and/or another component of therapeutic device 120 in a way that allows pressurized gas to be administered to and/or received from the user. Gas module 250 may include to a pressure vessel that may receive, contain, and/or administer a gas at a positive pressure (e.g. above ambient pressure). For example, gas module 250 may include a reservoir that may be filled with a compressed gas that, as further discussed herein, may be regulated to provide the gas to the user at a pressure below the pressure at which the gas is stored in the reservoir. Additionally, or alternatively, gas module 250 may include a pump (e.g. an electric pump, a hand-driven pump, etc.) that may generate pressurized gas, such as compressed air, for use by the therapeutic device 120. Gas module 250 may also, or alternatively, provide pressure to the user that is created when the user exhales. For example, a user may generate a pressure by exhaling (e.g. normally exhaling, exhaling in a manner similar to blowing up a balloon, etc) into a chamber (e.g. within housing 210, a chamber formed within nostrils by nasal pillows 240, etc) formed by therapeutic device 120. The pressure may be maintained by, for instance, seal 220 and/or nasal pillows 240. The pressure may be stored in the chamber and/or redirected to a reservoir of gas module 250 and used to provide gas pressure to the user (such as when inhaling and/or exhaling) as described herein. Additionally, or alternatively, the gas pressure may be used to create vibrations as described herein.

[0022] Gas module 250 may include a regulator (e.g. poppet valves, pressure regulation valves, single stage diaphragm pressure regulators, two stage diaphragm pressure regulators, spring-loaded regulators etc.) to control, the pressure and/or rate of flow at which a gas is applied
to the user. The pressure regulators may allow gas to be applied to the user at an ideal range of pressures, for example 4*25 centimeters of water (4-25 cm H2O), more ideally 4-10 cm H2O. The pressure regulator may change the pressure applied to the user. The gas module 250 may also, or alternatively, include one or more shutoff valves (e.g., gate valves, ball valves, globe valves, spring loaded shutoff valve, etc.) which may be operable (e.g. by user interface 211, etc.) to start and/or stop the flow of a gas from a gas source (e.g. a source of pressurized gas) to the user.

The gas module 250 may also modulate and/or oscillate the gas pressure applied to the user. Modulating the gas pressure applied to the user may create a gas pressure pulse that travels via the nasal interface into the nasal and/or sinus cavities. The gas module may modulate the gas pressure by controlling the shape of each pressure pulse. Such modulation may include controlling a rate at which the gas pressure rises, levels off, and/or falls as a function of time. The gas module may also, or alternatively, modulate the gas pressure by controlling pulse duration, duration between pulses, frequency of pulses, following a duty cycle associated with the pulses, etc. The modulating gas pressure pulses may break up and/or loosen the fluid, mucus, solids, or other obstructions within the nasal and/or sinus cavities of the user, which may promote drainage of the mucus. To modulate the gas pressure, the gas module 250 (or some other component of therapeutic device 120) may include, for example, a solenoid which may be operable to change the path the gas travels through the gas module 250. The solenoid may change the path of the gas from a first pressure regulator, which provide gas to the nasal interface at one pressure, to a second pressure regulator, which provide gas to the nasal interface at a different pressure and/or to a non-regulated passage through the gas module (which provides the gas at the pressure it is stored/created. Additional regulators (three, four, five, etc.) may be used
as well, which may include using three-position (or more) solenoids, multiple solenoids, or oilier ways of changing the path of the gas through the regulators. In this way, the pressure at which the gas is introduced to the user may be modulated, such as by operating a solenoid. Additionally, or alternatively, the gas module may include one or more pressure regulators which may be configured to switch, in response to an input (automatic and/or manual), between two or more pressures, or between pressure and no pressure (e.g., relative to ambient pressure), to oscillate the pressure of the gas delivered to the user. The gas module may vary the gas pressure and/or frequency of the modulation of gas pressure (e.g. based on a series of modulated pressure pulses associated with a wave form, frequency and/or duty cycle, etc.) to assist with breaking up and/or loosening of the fluid, mucus, solids, and/or obstructions to promote drainage of the nasal and/or sinus cavities and/or to restore Eustachian equilibrium. Varying the pressure of the gas and/or the frequency of modulation of the gas pressure may also, or alternatively, generate a gas-induced vibration, which may be applied to the nasal interface of the user in the same and/or similar fashion as the vibrations generated by vibration generator 230 (e.g. through nasal pillows 240, sea! 220, housing 210, etc.). In this embodiment, the gas module 250 may serve as the vibration generator 230 in that the gas module 250 creates vibrations by modulating the pressure applied to the user. Modulating the pressure (or, for instance, operating a solenoid valve) may cause the nasal interface (e.g. nasal pillows, etc.) to vibrate. Additionally, or alternatively, gas pressure may be modulated and/or gas vibration may be created by a user when exhaling via the nasal interface into the gas module 250, which may use the pressure generated from the exhale to generate a pressure and/or vibration as further described herein. Accordingly, gas pressure and/or gas-induced vibration may be created and/or controlled, within the therapeutic device based on the inhalation or exhalation of the user, by manual force supplied by the user (e.g., a
crank, etc.), and/or automatically the therapeutic device using an external power source (electrical power, etc.).

Power module 260 may include one or more power generation and/or power supply components. For example, power module 260 may include, for instance, a battery (e.g. a conventional direct current (DC) battery, etc.), a connection to an alternating current (AC) power source, such as a wall outlet, etc. Additionally, or alternatively, power module 260 may include manually powered devices that may be used to provide treatment as further described herein. For example, and not limitation, power module 260 may include a crank (e.g. a handle attached to a shaft, etc.) that may be used by a user to provide rotational energy (e.g. by turning the handle) to vibration generator 230. Vibration generator 230 may convert the rotational energy (e.g. energy from a rotating shaft) into vibrations, which may be applied to the nasal interface of the user. Additionally, or alternatively, power module 260 may include a turbine device (not shown) that generates rotational energy when the user exhales (e.g. the user exhales into, for example, housing 210 and the exhaled breath evacuates housing 210 across blades associated with the turbine device, etc.). The rotational energy from turbine device may be provided to vibration generator 230 to produce vibrations. Additionally, or alternatively, the power module 260 may include a balloon device which may be inflated by the user (e.g. by exhaling into therapeutic device 120, etc.). Balloon device may store pressure that may be used to obtain rotational energy from, for instance, turbine device. In addition to providing power to generate vibrations, power module 260 may provide power to, for instance, the user interface 211, valve 212 and associated components of housing 210, the gas module 250, medication module 270 and/or any other components of therapeutic device 120 that require electrical, mechanical, electromechanical, hydraulic, etc. power.
Medication module 270 may provide liquid, atomized, vaporized and/or powdered medication to the gas. The medication module may be connected to therapeutic device 120 (e.g. to gas module 250, housing 210, nasal pillows 240, etc.) via an air-tight connection (e.g., a hollow tube, manifold, a tee into a line associated with the gas module, etc.). The medication module may regulate the flow and/or dosage of medication, such as with a metering device, a nozzle associated with a certain cross section, etc. The medication module may include a mixing valve, a nozzle, injector, etc., which may vaporize, atomize and/or separate the medication prior to, during, and/or after the medication is applied to the user (e.g. applied directly to the user, mixed with gas from gas module 250 before being applied to user, etc.). Additionally, or alternatively, the mixing valve may uniformly distribute the medication within the gas.

The therapeutic device 120 may also, or alternatively, provide a temperature control module (not shown) which may warm, cool or otherwise control the temperature of the gas and/or medication delivered to the user via the nasal interface. The temperature control module may be connected to the gas module and/or the medication module via an air-tight connection (e.g., a tee into a line associated with the gas module and/or medication module, etc.). The temperature control module may include a heat exchanger which may apply heat to the gas and/or the medication to raise the temperature of the medication and/or the gas entering the nasal interface. Additionally, or alternatively, the temperature control module may utilize electrical resistors, which may convert electrical energy into heat energy, and which may apply heat to the gas and/or the medication to raise the temperature of the gas and/or medication. The temperature control module may cause a portion of the exhaled gas breathed by a user to be diverted to the gas that is to be conditioned to be provided to the user via the nasal interface.
The therapeutic device 120 may also, or alternatively, include a moisture control module (not shown) to provide humidified gas to the user via the nasal interface. The moisture control module may be connected to the therapeutic device via an airtight connection (e.g., a manifold, a tee in one of the lines associated with the therapeutic device, etc.). The moisture control module may combine moisture (e.g., tap water, distilled water, vapor, etc.) with the gas, medication and/or both, increasing the moisture and/or humidity of the gas entering; the nasal interface may enable the membranes within the nostrils, throat, and/or mouth to remain moist and/or to lubricate the nasal and sinus cavities of the patent. Increasing the moisture and/or humidity of the gas may also, or alternatively, break up and/or loosen the fluid, mucus, solids or obstructions within the nasal and/or sinus cavities of the user, which may promote drainage of the mucus. The moisture control module may include a humidifier (e.g., evaporative humidifier, impeller humidifiers, vaporizers, atomizing nozzles, ultrasonic humidifiers, forced-air humidifiers, etc) which may increase the humidity of the gas entering the nasal interface.

Figure 3 depicts the therapeutic device 120 of Figures 1 & 2 further including a cover 310. Cover 310 may surround and/or enclose one or more components of the therapeutic device 120. Cover 310 may, for instance, enclose housing 210 and the modules of therapeutic device. Cover 310 may include one or more apertures 311 which may allow a gas (e.g., gas from gas module 250, exhaled breath, air from the environment, etc) to enter and/or exit the therapeutic device 120. In the embodiment depicted in Figure 3, cover 310 may be designed to look like the trunk of an elephant or a child's toy (e.g., a giraffe, a superhero, etc.). Designing cover 310 in the shape of a child's toy may appeal to children who want to use therapeutic device 120. Cover 310 may also, or alternatively, include a user Interface penetration 312, which may allow a user to control the therapeutic device 120 via the user interface when the cover is mounted to, placed
over or otherwise installed on therapeutic device. In addition to surrounding and/or enclosing therapeutic device 120, cover 310 may also, or alternatively, reduce the noise associated with operating therapeutic device 120.

[0029] The systems and/or methods may enable the therapeutic device to administer one or more therapies to a user to treat a sinus and/or nasal condition and/or one or more symptoms associated with sinusitis (e.g., inflammation, edema, pain resulting from pressure in the sinus cavities, nasal mucus discharge, headaches, etc.) and/or to restore Eustachian equilibrium. For example, a user may position a nasal interface on, over, within, or around the nose and/or mouth of the user. In one embodiment, the nasal interface may include two nasal pillows, which may be positioned inside of the nose of the user. Additionally, or alternatively, the nasal interface may include a housing that may be placed around the nostrils and/or mouth of the user. When the user positions the nasal interface around and/or inside the nose, the nasal interface may create a seal that may maintain a pressure that may be applied to the user via the nasal interface.

[0030] The user may operate the therapeutic device (e.g., by flipping a switch, opening a valve, pressing a button, etc.) to cause the gas module to apply a gas (e.g., air, oxygen, nitrogen, helium, heSox, a combination of gasses, etc.) contained within and/or created by a gas source to the nasal interface. The gas module may include one or more pressure regulators which may regulate the gas applied to the nasal interface to be within a pressure range (e.g., 4-25 cm H2O). Additionally, or alternatively, the gas module may automatically ami/or by input from the user (e.g., by pressing a button, entering a preferred setting, etc via the user interface) modulate and/or oscillate the pressure at which the gas is applied to the nasal interface and may vary the frequency at which the pressure is modulated and/or oscillated. The modulation and/or oscillation of the gas pressure applied to the user at the nasal interface may cause a gas pulse
and/or gas vibration, the frequency of which may be changed (e.g., increased, decreased, or varied) by the gas module.

[0031] Gas may flow from the gas module to the nasal interface. The seal may maintain the pressure created at the nasal interface by the application of the gas by the gas module. A valve may limit the pressure created at the nasal interface and/or may prevent the pressure within a cavity from exceeding a limit (such as when the user exhales into cavity). Additionally, or alternatively, the gas module and/or the seal may maintain a specific pressure at the nasal interface when the user inhales and/or exhales. The pressure applied to the user by the gas, as well as pressure changes resulting from the modulated gas pressure and/or exhaling by the user, may break up and/or loosen mucus within the nasal and/or sinus cavities of the user, which may promote drainage of the mucus and/or may treat one or more symptoms associated with sinusitis (e.g., inflammation, edema, pain resulting from pressure in the sinus cavities, nasal mucus discharge, headaches, etc.) and/or may restore Eustachian equilibrium.

[0032] The therapeutic device may cause the nasal interface to mechanically vibrate and thereby transfer vibratory forces to the face, nose, and/or month, as well as the nasal and/or sinus cavities of user. The user may provide input to the therapeutic device, e.g., via a user interface, to control the strength and/or rate of the vibration. Such control may enable the user to increase, decrease or maintain the vibratory forces that are imparted on the user. Mechanical vibration may be applied to the user along with and/or without the gas pressure from the gas module.

[0033] The user may operate a medication module (e.g., by interacting with the user interface, depressing a button on medication module, etc.) of the therapeutic device to apply a medication (e.g., vaporized medications, powdered medications, etc.) to the user. The medication may break up and/or loosen mucus within the nasal and/or sinus cavities of the user.
which may promote drainage of the mucus and/or may treat one or more symptoms associated with sinusitis (e.g., inflammation, edema, pain resulting from pressure in the sinus cavities, nasal mucus discharge, headaches, etc.). The medication module may apply medication to the nasal interface with or without gas from the gas module. The medication module may vaporize and/or separate medication before it is applied to the nasal interface. The medication module may uniformly mix the medication with the gas.

[0034] The user may operate a temperature module to increase and/or decrease the temperature of the gas and/or the medication applied to the user at the nasal interface. The temperature control module may apply heat to the gas, the medication, or both before it enters the nasal interface. Increasing and/or decreasing the temperature of the gas and/or medication may break up and/or loosen mucus within the nasal and/or sinus cavities of the user, which may promote drainage of the mucus, and/or may treat one or more symptoms associated with sinusitis (e.g., inflammation, edema, pain resulting from pressure in the sinus cavities, nasal mucus discharge, headaches, etc)

[0035] The user may operate a humidity module to increase and/or decrease the humidity of the gas, the medication or both applied to the user at the nasal interface. Increasing the humidity of the gas, the medication or both may break up and/or loosen mucus within the nasal and/or sinus cavities of the user, which may promote drainage of the mucus, and/or may treat one or more symptoms associated with sinusitis.

[0036] The user may operate a power module which may provide mechanical power used to generate vibrations (e.g. via a vibration generator) to be delivered to the user via the nasal interface. The vibrations may break up and/or loosen mucus within the nasal and/or sinus cavities of the user, which may promote drainage of the mucus. Additionally, or alternatively,
the vibrations may open the ear canal to relieve pressure from the ear drum, which may be created by an infection, mucus, and/or changes in pressure (e.g., taking off and/or landing in an airplane). In another embodiment, the power module may include a manually driven (e.g., by the user's breath, the user's hand, etc.) vibration device, may be shaped like a child's toy (e.g., an elephant, a giraffe, a superhero, etc.) and may be used by children to alleviate the discomfort associated with the loss of Eustachian equilibrium, such as during air travel.

[0037] The foregoing description provides illustration and description, but is not intended to be exhaustive or to limit the implementations to the precise form disclosed. Modifications and variations are possible in light of the above disclosure or may be acquired from practice of the embodiments.

[0038] It will be apparent that the apparatus, systems, methods, technologies and/or techniques, as described above, may be implemented in many different forms of hardware and/or software in the implementations described herein and illustrated in the figures. The actual or specialized hardware and/or materials used to implement the apparatus, systems, methods, technologies and/or techniques is not limited to the embodiments; it should be understood that hardware, software and/or materials may be designed to implement the apparatus, systems, methods, technologies and/or techniques based on the description herein.

[0039] It should be emphasized that the terms "comprises" / "comprising" when used in this specification are taken to specify the presence of stated features, integers, steps or components but does not preclude the presence or addition of one or more other features, integers, steps, components, or other groups thereof.

[0040] Even though particular combinations of features are recited in the claims and/or disclosed in the specification, these combinations are not intended to limit the disclosure of the
embodiments, In fact, many of these features may be combined in ways not specifically recited in the claims and/or disclosed in the specification!. Although each dependent claim listed below may directly depend on only one other claim, the disclosure of the embodiments includes each dependent claim in combination with every other claim in the claim set.

No element, act or instruction used in the present application should be construed as critical or essential to the embodiments unless explicitly described as such. Also, as used herein, the articles "a" and "an" are intended to include one or more items and may be used interchangeably with "one or more." Where only one item is intended, the term "one" or similar language is used. Further, the phrase "based on" is intended to mean "based, at least in part, on" unless explicitly stated otherwise,
WHAT IS CLAIMED IS:

1. A therapeutic device for treating one or more conditions associated with a user's Basal cavities, sinuses, and/or ear canals, the therapeutic device comprising:
   - a vibration generator configured to provide a vibration to a nasal interface of the user, the nasal interface located over a nose, amend the nose or in the nose of the user;
   - a gas module configured to provide a gas having a positive pressure to the user at a chamber;
   - a seal configured to maintain the positive pressure at the chamber;
   - a power module configured to provide power to the vibration generator to create the vibration; and
   - a housing which the user may hold and which is connected to the vibration generator, the gas module, and the power module.

2. The therapeutic device of claim 1 farther including a user interface mounted to the housing and operable by the user to control one or more of the following functions of the therapeutic device:
   - increase the positive pressure of the gas;
   - decrease the positive pressure of the gas;
   - modulate the positive pressure of the gas;
   - increase the frequency of the modulation of the positive pressure of the gas;
   - decrease the frequency of the modulation of the positive pressure of the gas;
   - turn on the positive pressure of the gas;
   - turn off the positive pressure of the gas;
   - increase the vibration produced by the vibration generator; or
decrease the vibration produced by the vibration generator.

3. The therapeutic device of claim 1 where the gas module serves as the vibration generator by modulating the positive pressure of the gas.

4. The therapeutic device of claim 1 further including a medication module configured to provide a medication to the user.

5. The therapeutic device of claim 4 further including a user interface mounted to the housing and operable by the user to control one or more of the following functions of the therapeutic device:
   - turn on the medication module to provide medication to the user;
   - turn off the medication module to stop medication from being provided to the user;
   - increase the amount of medication provided to the user via the medication module;
   - or decrease the amount of medication provided to the user via the medication module.

6. The therapeutic device of claim 1 where the seal is located on the housing.

7. The therapeutic device of claim 6 where the chamber is located within the housing.

8. The therapeutic device of claim 1 further including a nasal pillow extending from the housing and connected to the vibration generator.

9. The therapeutic device of claim 8 where the seal is located on the nasal pillow and the chamber is located within a nostril associated with the nasal pillow.

10. The therapeutic device of claim 8 where the vibration is delivered to the user via the nasal pillow.

11. The therapeutic device of claim 8 where the nasal pillow further includes a ballast.
12. The therapeutic device of claim 1 where the power module provides power generated by
the breath of the user or a crank operated by the user to the vibration generator to provide the
vibration to the user.
13. The therapeutic device of claim 2 where the power module provides electrical power to
the vibration generator.
14. The therapeutic device of claim 12 where the power module provides power in the form
of rotational power.
15. The therapeutic device of claim 1 further including at least one of the following:
   a temperature control module to warm the gas; or
   a humidity control module to increase or decrease the humidity of the gas.
16. The therapeutic device of claim 1 where the gas is one or more of the following:
   air,
   oxygen,
   nitrogen,
   helium,
   carbon dioxide,
   water vapor,
   exhaled breath of the user, or
   heliox.
17. The therapeutic device of claim 1, where the positive pressure of the gas is from four to
twenty-five centimeters of water.
18. The therapeutic device of claim 1, where the positive pressure of the gas is from four to
ten centimeters of water,
19. The therapeutic device of claim 1 further including a valve that prevents the positive pressure in the chamber from exceeding a threshold.

20. A manually operated therapeutic device for treating one or more conditions associated with a user's nasal cavities, sinuses, and/or ear canals, the manually operated therapeutic device comprising:

   a vibration generator configured to provide a vibration to a nasal interface of the user located over a nose, around the nose or in the nose of the user;

   a power module configured to provide power generated by the user to the vibration generator;

   a gas module configured to provide a gas having a positive pressure to the user at a chamber, the gas module including a reservoir tillable by exhaled breath of the user to provide the positive pressure of the gas;

   a seal configured to maintain the positive pressure at the chamber; and

   a housing that the user may hold and that is connected to the seal, the vibration generator, the power module and the gas module.

21. The therapeutic device of claim 19 where the power generated by the user comes from the exhaled breath of the user or a crank rotated by the user.

22. The therapeutic device of claim 19 further including a cover.

23. A method for treating one or more conditions associated with a user's nasal cavities, sinuses, and/or ear canals, the method comprising:

   providing a therapeutic device including

   a vibration generator configured to provide a vibration to a nasal pillow located at a nasal interface of the user, the nasal interface located in a nose of the user;
a gas module configured to provide a gas having a positive pressure to the user at a chamber; and

a seal configured to maintain the positive pressure at the chamber;

operating the therapeutic device to provide the vibration to the nasal pillow; and
operating the therapeutic device to provide the gas to the chamber.
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/51484

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61 M 15/08 (2017.01)
CPC - A61 M 16/0006, A61 M 15/08, A61 M 2210/0618, A61 H 2205/023, A61 H 2201/165, A61 H 2201/0165

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
See Search History Document
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tbody>
<tr>
<td>A</td>
<td>US 2013/0012869 A1 (CHA et al.); 10 January 2013 (10.01.2013); entire document, especially Figs. 2, 5, 8; Abstract; para. [0046], [0057], [0063].</td>
<td>1-23</td>
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<tr>
<td>A</td>
<td>US 2012/0085344 A1 (LUBER et al.); 12 April 2012 (12.04.2012); entire document, especially Figs. 2, 4; Abstract; paras. [0105]-[0106].</td>
<td>1-23</td>
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<td>A</td>
<td>US 2008/0208488 A1 (AVNI); 21 August 2008 (21.08.2008); entire document.</td>
<td>1-23</td>
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<tr>
<td>A</td>
<td>US 2011/0120456 A1 (IMMEL); 26 May 2011 (26.05.2011); entire document.</td>
<td>1-23</td>
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<tr>
<td>A</td>
<td>US 2013/0158451 A1 (JUTO et al.); 20 June 2013 (20.06.2013); entire document.</td>
<td>1-23</td>
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:
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  * "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
26 October 2017

Date of mailing of the international search report
29 NOV 2017

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