

AN AIRWAY CLEARANCE DEVICE

TECHNICAL FIELD

The present disclosure generally relates to an apparatus used for an airway clearance
5 therapy (ACT) and a method of using the same.

BACKGROUND

Mucociliary clearance (MCC) describing the self-cleaning mechanism of the airways typically involves the mucociliary escalator which serves to mobilize secretions, thus
10 preventing airways obstructions and maintaining optimal function of the respiratory system. In healthy individuals, 10–100 mL of airway secretions are continuously produced and cleared by the mucociliary escalator. This mucus clearance mechanism may be compromised by a variety of factors, including pathophysiological conditions affecting the mucociliary escalator such as bronchiectasis and ciliary dyskinesia and pulmonary disorders that alter the production and
15 composition of mucus (such as cystic fibrosis and COPD). The resulting stasis of secretions obstructs conducting airways, providing a nidus for recurrent infections and inflammatory responses, leading to repeated insults to the airways and parenchyma. Hence, regular use of ACTs and devices are critical for effective mucus mobilization and expectoration. This helps to prevent or at least minimize recurrent infections thereby preserving long-term lung function.

20 Conventional ACTs typically employ physical and mechanical means to manipulate airflow in the lungs, in order to mobilize secretions from the distal airways and towards the central airways, where evacuation is effected by coughing. Physical manipulations include breathing manoeuvres, postural drainage, and manual techniques. Mechanical devices, including chest percussion devices and oscillatory pressure devices, function on principles of
25 altering airflow, leading to and/or generating a cough-like effect. Regardless of the type of intervention, conventional ACTs are commonly driven by patient effort and involve active participation in therapy. They are time-consuming and generally arduous for the patient. Thus, conventional ACT modalities are likely responsible for poor adherence to the prescribed therapy. The use of devices and prescribed therapies may require active patient involvement
30 for two to six hours daily. This has been described as a major factor contributing to reduced compliance rates of ACT in cystic fibrosis (CF) patients.

Further, the majority of the ACT devices function via exhalation through the mouth. This requires active patient coordination, effort and physical fitness or lung capacity to generate the desired therapeutic effect. Patients with moderate to severe obstructive lung diseases often lack appropriate physical fitness and lung capacities thus constantly suffer from shortness of
5 breath. Nasal breathing as a form of pulmonary rehabilitation is recommended for these patients to alleviate shortness of breath symptoms.

Oral, hand-held ACT devices also require the patients to generate and sustain greater than 30 L/min exhalation flow rates, breathe through these devices continuously for greater than 20 minutes per session, and require multiple sessions per day to obtain therapeutic effects,
10 resulting in post-therapy breathlessness and fatigue. These devices are thus unsuitable for this group of patients. In addition, oral ACT technologies suffer from compromised therapy effectiveness and low adherence. Furthermore, patients will frequently expectorate mucus throughout the therapy which results in the disruption of the seal at device-oral interface, leading to additional therapy steps and increased time.

At present, patients need to exclusively perform ACT for a prescribed duration, rendering them incapable of pursuing other activities while ACT is ongoing. Additionally, these therapies depending on severity are applied externally through automated pressurised airflow machines including the cough assist machine, intrapulmonary percussive ventilators (IPV), or high frequency chest wall oscillations. Significant drawbacks of these include need
15 of skilled practitioner to adequately apply therapy, the risk of barotrauma, and are very bulky and heavy, which then in turn add further strain and discomfort to the patient during therapy. In more severe cases, some patients require automated pressurized airflow machines such as CPAP machines to make up for the therapeutic inadequacies of conventional ACT technologies. However, the externally automated pressurized airflow technologies that
20 complement the use of conventional ACT devices are primarily used to treat sleep apnoea and thus, can only generate and deliver systemic continuous pressure flows which are in no form intended to facilitate airway clearance. These technologies are also incapable of generating oscillating pressure waveforms required to mobilize mucus plugs within the bronchial tree and are not designed to be used in situ with conventional nasal PEP and O-PEP devices as part of
25 ACT.
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In view of the above, there is an urgent clinical unmet need for an easy, effortless, and effective sputum clearance therapy in a significant portion of patients with chronic respiratory

diseases. The drawbacks on therapy effectiveness, ease, independence, user-lifestyle integration and time saving described in the existing modalities are overcome using the airway clearance device described in the present disclosure.

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SUMMARY

The current disclosure provides an airway clearance device. The airway clearance device may comprise an airflow inlet to guide the direction of airflow to the device during exhalation and an airflow obstruction mechanism, configured to receive the airflow from the airflow inlet and to generate a positive expiratory pressure (PEP) via a cavity of a respiratory conducting passage in a subject. According to some embodiments of the disclosure, the airflow obstruction mechanism comprises an airflow outlet.

Optionally, the device may further comprise an airflow resistance mechanism in fluid communication with the airflow outlet and the airflow obstruction mechanism, wherein said airflow obstruction mechanism and airflow resistance mechanism are configured to generate the PEP via the cavity of the respiratory conducting passage. According to some embodiments of the disclosure, the PEP is an oscillatory PEP or O-PEP. Optionally, the airflow obstruction mechanism may be actuated by a mechanical means or an electromechanical means causing motion of the airflow obstruction mechanism. When said airflow obstruction mechanism is actuated by the electromechanical means, the device may further comprise a power transmitter configured to transmit the power from a motion generator to the airflow obstruction mechanism causing motion of the airflow obstruction mechanism. According to some embodiments of the disclosure, the motion may be a linear motion or a rotating motion. The motion generator may be an oscillatory generator, configured to create an oscillatory motion thereby generating the PEP. Optionally, the motion generator is configured to operate with a frequency in a range from 0.5 Hz to 200 Hz. The mechanical means may be selected from the group consisting of crank gear and spring.

The airflow obstruction mechanism may comprise at least one component selected from the group consisting of one or a plurality of port, one or a plurality of flap, one or a plurality of fin, one or a plurality of vane, one or a plurality of disc, one or a plurality of rod and combinations thereof to obstruct the airflow during exhalation. Optionally, the one or the plurality of port, the one or the plurality of flap, the one or the plurality of fin, the one or the plurality of vane, the one or the plurality of disc and the one or the plurality of rod may comprise

a curved portion. Optionally, the at least one component may be disposed radially or axially relative to the vertical axis positioned at the center of the airflow obstruction mechanism.

Optionally, the at least one of the airflow inlet, the airflow obstruction mechanism, the airflow resistance mechanism and the airflow outlet may be enclosed within a housing.

5 Optionally, the airflow obstruction mechanism may be connected to the power transmitter via a connecting means. The connecting means may comprise a magnet array disposed at the outer surface of the housing.

10 According to some embodiments of the disclosure, the airflow resistance mechanism may comprise at least one component selected from the group consisting of one or a plurality of port, one or a plurality of flap, one or a plurality of fin, one or a plurality of vane, one or a plurality of disc, one or a plurality of rod and combinations thereof to provide a resistance to the airflow during exhalation.

According to some embodiments of the disclosure, the PEP generated may be transmitted into the airway via a nasal interface.

15 Optionally, the device disclosed herein may further comprise a pressure relief mechanism to vent excess pressure in the device higher than a threshold value, said pressure relief mechanism connecting the nasal interface and the airflow inlet. The threshold value may be up to 60 cm H₂O.

20 There is also provided a system comprising the airway clearance device defined in the current disclosure.

Further, there is provided a method for clearing airway in a subject. The method may comprise providing the device described in the current disclosure and introducing air generated during exhalation to the device via the airflow inlet. The method may further include generating a positive expiratory pressure (PEP) in the device and transmitting generated PEP via a cavity of a respiratory conducting passage in the subject. Optionally, pressure within the cavity may be adjustable from 5 to 50 cmH₂O at standard conditions. The PEP generated may have a volumetric flowrate in a range from 6 L/min to 100 L/min under at-rest physiological breathing. According to some embodiments of the disclosure, the PEP is an oscillatory PEP (O-PEP).

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Advantageously, the PEP generated by the device disclosed herein may not result in breathing exertion and user fatigue due to inability in sustaining airflow requirements, particularly for a majority of patients having moderate to severe obstructive lung diseases who often lack appropriate physical fitness and lung capacities and constantly suffer from shortness of breath. Further advantageously, unlike the existing devices, the device disclosed herein does not require constant sealing and immense patient effort and/ or care-giver effort.

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Still advantageously, using at-rest physiological nasal breathing, the variable active therapeutic PEP and/or O-PEP waveforms generated are delivered in a more comfortable manner in comparison to conventional forced oral breathing methods. Further advantageously, the device and system disclosed herein may have the ability of interfacing with the human nose in a user-friendly and comfortable manner either intra-nasally or extra-nasally. Additionally, the device or the system disclosed herein may be secured in either a hand-held manner or worn on the user's body that is hands-free with an unobstructed securement on the face for extended period of use. Additionally, the device or the system disclosed may create an easy and effective therapy experience. Further advantageously, part or all components of the nasal assembly or device may be cleaned and sterilized after each use and can be re-used and/or made to be disposable.

BRIEF DESCRIPTION OF THE DRAWINGS

Some non-limiting exemplary embodiments or features of the disclosed subject matter are illustrated in the drawings.

In the drawings:

FIGS. 1A-1B illustrate the accommodation of the airway clearance device, in accordance with some embodiments of the present disclosure;

FIG. 2A-2C illustrate the airway clearance device, in accordance with some embodiments of the present disclosure, assembled with other parts or elements to form the nasal assembly system; FIG. 2A is a front view thereof; FIG. 2B is a top view thereof; and FIG. 2C is a perspective exploded view of parts or elements of the nasal assembly system;

FIG. 3A illustrates the airway clearance device having ports, in accordance with some embodiments of the present disclosure;

FIG. 3B illustrates the airway clearance device having a respiration gate and base, in accordance with some embodiments of the present disclosure;

FIGS. 4A-4B illustrate the airway clearance device comprising the housing, in accordance with some embodiments of the present disclosure;

FIGS. 5A-5B illustrate the airway clearance device comprising the airflow obstruction mechanism and the airflow resistance mechanism, in accordance with some embodiments of the present disclosure;

FIG. 6A illustrates the right-side perspective view of the airway clearance device showing the nasal pillow, air outlet, motor housing and airflow resistance mechanism, in accordance with some embodiments of the present disclosure;

FIG. 6B illustrates the right-side perspective view of the airway clearance device described in FIG. 6A, without the housing, showing the airflow obstruction mechanism and motor to actuate the airflow obstruction mechanism, in accordance with some embodiments of the present disclosure;

FIG. 6C illustrates the top view of the airway clearance device described in FIG. 6B;

FIGS. 7A-7G illustrate the perspective view of various profile of the airflow obstruction mechanism of the airway clearance device, in accordance with some embodiments of the present disclosure;

FIGS. 8A-8F illustrate the top view of various profile of the airflow obstruction mechanism of the airway clearance device, in accordance with some embodiments of the present disclosure;

FIGS. 9A-9B illustrate the perspective view of various profile of the airflow obstruction mechanism of the airway clearance device, in accordance with some embodiments of the present disclosure; and

FIG. 10 illustrates a block diagram depicting interactions between the parts or elements of the airway clearance device, in accordance with some embodiments of the present disclosure.

Identical or duplicate or equivalent or similar structures, elements, or parts that appear in one or more drawings are generally labelled with the same reference numeral, optionally with an additional letter or letters to distinguish between similar entities or variants of entities, and may not be repeatedly labelled and/or described. References to previously presented elements are implied without necessarily further citing the drawing or description in which they appear.

Dimensions of components and features shown in the figures are chosen for convenience or clarity of presentation and are not necessarily shown to scale or true perspective. For convenience or clarity, some elements or structures are not shown or shown only partially and/or with different perspective or from different point of views.

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DETAILED DESCRIPTION

The present disclosure provides an airway clearance device. Advantageously, the device is useful to loosen and/ or mobilize biofluid as well as for assisted expectoration. Further advantageously, the device disclosed herein may be incorporated into a nasal assembly system
10 for administering a range of therapeutic pressure waveforms or percussions. In some embodiments, said range of therapeutic pressure waveforms or percussions are delivered via positive expiratory pressure (PEP). In some embodiments, said PEP is a variable PEP. In some embodiments, said variable PEP is nasal PEP or oral PEP. In some embodiments, the PEP is an oscillatory PEP or O-PEP. In some embodiments, the device may be used in situ with other
15 externally generated therapies including but not limited to oscillatory waveforms (o-therapies), nebulizers or medications for chronic mucus clearance.

In some embodiments, the device disclosed herein may be in the formfactor of either a handheld device or worn on a user's body. In some embodiments, the device may be accommodated on a user's head, face, ears or other parts of the body including neck, back or
20 hip. In some embodiments, said device may be used for therapy and therefore such a device may be termed as a respiratory therapy device. In some embodiments, the device is useful for airway clearance therapy (ACT).

In some embodiments, the device disclosed herein is designed to generate PEP including O-PEP. In some embodiments, the generated PEP may be within the nasal cavity
25 when air flows through the exhalation ports during a respiration cycle. In some embodiments, the generated PEP may be both oscillatory and non-oscillatory in nature depending on the airflow obstructors or airflow obstruction mechanism employed. In addition, the device defined herein may be used for a variety of respiratory conditions such as bronchiectasis, cystic fibrosis, chronic obstructive pulmonary disease or other conditions that lead to increased mucus
30 production and difficulty in clearing sputum from the distal deep lung airways to the more proximal airways. The trapped sputum may lead to significant patient breathlessness and is a

nidus for infection, leading to further exacerbations of infection and an increased frequency of longer hospital stays.

In terms of clinical therapeutic effect, PEP produces a constant static backpressure into the lungs in order to maintain patency of the airways especially in the distal regions. On the other hand, in the case of O-PEP, in addition to maintaining patency of the airways, the oscillatory nature of percussive waveforms as compared to the static backpressure in PEP allows for a more efficacious mobilisation and liquification of sputum occluding the airways as compared to PEP, as well as a more comfortable user experience.

In some embodiments, the PEP or O-PEP generated by the device disclosed herein may be transmitted via an air column from the nasopharynx to the trachea and finally to the bronchioles of the distal airways. In some embodiments, the percussive pressure waves may facilitate the movement or mobilization of sputum from the distal airways into the central airways, allowing the patient or subject to cough out the said trapped sputum to either be expectorated or swallowed.

In some embodiments, the generated PEP or O-PEP may have a volumetric flowrate in a range from 6 L/min to 100 L/min under at-rest physiological breathing, for example 6 L/min, 8 L/min, 10 L/min, 15 L/min, 20 L/min, 25 L/min, 30 L/min, 35 L/min, 40 L/min, 45 L/min, 50 L/min, 55 L/min, 60 L/min, 65 L/min, 70 L/min, 75 L/min, 80 L/min, 85 L/min, 90 L/min, 95 L/min or 100 L/min.

In some embodiments, the pressure within the cavity is adjustable from 5 to 50 cmH₂O at standard conditions, for example about 5 cmH₂O, about 10 cmH₂O, about 15 cmH₂O, about 20 cmH₂O, about 25 cmH₂O, about 30 cmH₂O, about 35 cmH₂O, about 40 cmH₂O, about 45 cmH₂O or about 50 cmH₂O.

As discussed above, patients having moderate to severe obstructive lung diseases lack appropriate physical fitness and lung capacities which results in them constantly suffering from shortness of breath. Clinical and pulmonary rehabilitation for such patients involve nasal breathing to alleviate these said symptoms. Therefore, conventional oral breathing powered and non-powered therapies, which are used for sputum and airway clearance, would require continuous prolonged large volume airflows through the mouth. This would lead to patients suffering from post-therapy fatigue and breathlessness along with mouth dryness. The airway clearance device disclosed herein can be used to overcome the above drawbacks by utilizing the physiological respiratory anatomical structure of the nasal passage for easy and effective

delivery of airway clearance therapy. In some embodiments, therapy delivery via the nasal passage may also have the potential to positively benefit patients with mucus clearance issues in the upper respiratory tract such as chronic sinusitis and/or chronic rhinitis.

5 In some embodiments, the airway clearance device comprises an airflow inlet and an airflow obstruction mechanism or airflow obstructor. In some embodiments, the airflow inlet is configured to guide the direction of airflow to the device during exhalation. In some embodiments, the airflow obstruction mechanism is configured to receive the airflow from the airflow inlet and to generate a positive expiratory pressure (PEP) via a cavity of a respiratory conducting passage in a subject. In some embodiments, the airflow obstruction mechanism
10 comprises an airflow outlet.

In some embodiments, optionally, the device may comprise a housing to enclose or encase at least part of the airflow inlet, airflow outlet and airflow obstruction mechanism. In some embodiments, the housing may enclose the airflow inlet and the airflow obstruction mechanism. In some embodiments, the housing may enclose or encase the airflow inlet, the
15 airflow obstruction mechanism and an airflow resistance mechanism. In some embodiments, the housing may additionally enclose a nasal interface and an airflow outlet. In some embodiments, said device is used to reduce accumulation or stasis of mucus in a respiratory system of a subject. In some embodiments, the nasal interface is in fluid communication with nose of the subject or part thereof.

20 In some embodiments, the housing serves as the base and support structure onto which all the elements of the device are disposed. In some embodiments, the housing interacts with the one or more elements on different ends using mechanisms such as but not limited to snap-fits, threads, screws, friction, adhesives, magnets or any other tightening mechanisms or combination thereof. The elements or components of the device including the nasal interface,
25 pressure-relief safety mechanism, oscillatory/rotational generation mechanism, power transmission mechanism, securement installations, airflow inlet and airflow outlet can be configured in the following combinations: encased within the housing and/or disposed on the exterior of the housing or external to the housing but still maintaining fluidic and/or mechanical communication with the oscillatory/rotational airflow obstruction mechanism and the airflow
30 resistance mechanism.

In some embodiments, the airflow obstruction mechanism includes a powered obstruction mechanism and a manually actuated obstruction mechanism. In some

embodiments, said airflow obstruction mechanism is actuated by a mechanical means or an electromechanical means thereby causing motion of the airflow obstruction mechanism. In some embodiments, the mechanical means is selected from the group consisting of crank gear and spring. In some embodiments, the motion is a linear motion or a rotating motion. In some
5 embodiments, when said airflow obstruction mechanism is actuated by the electromechanical means, the device further comprises a power transmitter that is configured to transmit the power from a motion generator to the airflow obstruction mechanism causing motion of the airflow obstruction mechanism. In some embodiments, the motion generator is an oscillatory generator that is configured to create an oscillatory motion thereby generating the PEP or O-PEP. In some
10 embodiments, the motion generator is a rotational generator that is configured to create a rotational motion thereby generating the PEP. In some embodiments, the motion generator is configured to operate with a frequency in a range from 0.5 Hz to 200 Hz for example 0.5 Hz, 1 Hz, 2 Hz, 5 Hz, 10 Hz, 20 Hz, 30 Hz, 40 Hz, 50 Hz, 60 Hz, 70 Hz, 80 Hz, 90 Hz, 100 Hz, 120 Hz, 140 Hz, 150 Hz or 200 Hz. In some embodiments, the airflow obstruction mechanism
15 is devoid of the power transmitter. In such embodiments, the airflow obstruction mechanism may not require the power transmitter. Hence, such airflow obstruction mechanism may be considered to work passively or is independent of the power transmitter.

In some embodiments, said airflow obstruction mechanism comprises at least one component selected from the group consisting of one or a plurality of port, one or a plurality
20 of flap, one or a plurality of fin, one or a plurality of vane, one or a plurality of disc, one or a plurality of rod and combinations thereof to obstruct the airflow during exhalation. In some embodiments, each of the one or one of a plurality of port, one or a plurality of flap, one or a plurality of fin, one or a plurality of vane, one or a plurality of disc and one or a plurality of rod may comprise curved portion. In some embodiments, the airflow obstruction mechanism
25 may comprise screw threading or helical or worm gearing. In some embodiments, the at least one component is disposed radially or axially relative to the vertical axis positioned at the center of the airflow obstruction mechanism. In an exemplary embodiment, the airflow obstruction mechanism comprises a shaft positioned in vertical direction, disposed substantially at the center of the airflow obstruction mechanism. In some embodiments, the
30 shaft may have a circular or rectangular cross section. It is to be understood that if the shaft has a circular cross section, the shaft may be a rod. In some embodiments, though in practice the at least one component may be attached or coupled along the length of the shaft, preferably the at least one component is attached along part of the length of the shaft. FIGS. 3A-3B show an embodiment of the PEP unit with a port system (222). The respiration gate (228) is used to

direct air in or out during breathing using the inhalation opening or the exhalation PEP ports. The ports are present on a cap-base component pair (226) and vary pressure by aligning the 'cap-ports' over the 'base ports'.

5 In some embodiments, the airflow obstruction mechanism may be an oscillatory or rotational airflow obstruction mechanism. In some embodiments, the airflow obstruction mechanism is in fluidic communication with the airflow inlet and the airflow resistance mechanism. In some embodiments, the airflow obstruction mechanism, the airflow inlet and the airflow resistance mechanism may be interconnected by a transmission conduit including but not limited to waveguides, pipes, tubes, adapters. Other suitable transmission conduits may
10 also be used. In some embodiments, the transmission conduit including but not limited to waveguides, pipes, tubes, adapters may be made of one or more biocompatible materials. In some embodiments, the airflow obstruction mechanism may be in mechanical communication with the power transmission mechanism. Advantageously, when the airflow obstruction mechanism is coupled with the airflow resistance mechanism, the power transmission
15 mechanism and the motion generation mechanism, this combination synergistically generates variable nasal PEP and/or O-PEP waveforms. In some embodiments, the variable nasal O-PEP waveforms are sinusoidal, square and/or any form of pulsing in nature, with frequencies ranging from about 0.5 Hz to about 200 Hz for example 0.5 Hz, 1 Hz, 2 Hz, 5 Hz, 10 Hz, 20 Hz, 30 Hz, 40 Hz, 50 Hz, 60 Hz, 70 Hz, 80 Hz, 90 Hz, 100 Hz, 120 Hz, 140 Hz, 150 Hz or 200
20 Hz.

In some embodiments, during exhalation including dynamic exhalation, the fluidic flow obstruction and/or disruption mechanisms may generate variable nasal PEP or O-PEP waveforms. In some embodiments, the at least one component of the fluidic flow obstructors is configured to move for example by rotating or oscillating with a frequency in a range of
25 about 0.5 Hz to about 200 Hz. In some embodiments, the motion is generated or created by the oscillatory or rotational generation mechanism. In some embodiments, the power transmission mechanism may transmit the oscillatory or rotational motion created by the motion generation mechanism to the airflow obstruction mechanism. In some embodiments, the motion transmitted may be both oscillatory and rotational motion.

30 In some embodiments, the degree of fluidic flow obstruction, interruption and/or disruption may be adjusted as necessary. In some embodiments, the degree of obstruction may be adjusted by way of at least one of the followings: increasing or decreasing the number of ports, flaps, fins, vanes and discs, changing the geometry of said ports, flaps, fins, vanes and

discs, changing the dimensions of said ports, flaps, fins, vanes and disks, and changing the type of materials.

In some embodiments, the airflow obstruction mechanism or at least part thereof may be encased within the housing and secured using suitable mechanisms including but not limited to snap-fits, threads, screws, adhesives, magnets or any other forms of mechanical bonding.

In some embodiments, the airflow inlet of the device disclosed herein is in fluid communication with a pressure-relief safety mechanism and the airflow obstruction mechanism. In some embodiments, the airflow inlet, the pressure-relief safety mechanism and the airflow obstruction mechanism are interconnected by way of one or more waveguides, pipes, tubes, adapters or other transmission conduits. In some embodiments, such transmission conduit is manufactured using bio-compatible materials. In some embodiments, the airflow inlet functions as an orifice and/or channel that guides the direction of airflow during exhalation from a nasal interface and pressure-relief safety mechanism, into the airflow obstruction mechanism. In some embodiments, the airflow inlet is to guide the direction of airflow from a top casing during exhalation to the airflow obstruction mechanism.

In some embodiments, the pressure-relief safety mechanism is in fluid communication with the airflow inlet and a nasal interface. In some embodiments, the pressure-relief safety mechanism, the airflow inlet and the nasal interface are interconnected by way of waveguides, pipes, tubes, adapters or other transmission conduits. In some embodiments, the transmission conduit is manufactured using bio-compatible materials. In some embodiments, the pressure-relief safety mechanism houses a check-valve that activates and vents out excess pressure upon reaching a preset threshold pressure in order to prevent a pressure build-up within the device and also the nasal cavity. In some embodiment, the pressure-relief safety mechanism is set with a threshold to vent excess pressure not exceeding about 20 cmH₂O, about 30 cmH₂O, about 40 cmH₂O, about 50 cmH₂O or about 60 cmH₂O. In some embodiment, the pressure-relief safety mechanism is set with the threshold to vent excess pressure up to about 30 cmH₂O. In some embodiments, the pressure-relief safety mechanism is set with the threshold to vent excess pressure up to about 40 cmH₂O. In some embodiments, the pressure-relief safety mechanism is set with the threshold to vent excess pressure up to about 50 cmH₂O. In some embodiments, the pressure-relief safety mechanism is set with the threshold to vent excess pressure up to about 50 cmH₂O.

In some embodiments, the device optionally further includes the nasal interface. In some embodiments, the nasal interface is a seal between the nose and the rest of the components of the device. Advantageously, the nasal interface avoids or at least reduces the leakage of delivered PEP and other generated therapies. In some embodiments, the reduction of leakage is achieved by contouring onto various (including customized) nose and/or nostril shapes with a tight and comfortable sealing. In some embodiments, the nasal interface is either intra-nasal or extra-nasal.

In an embodiment, the nasal interface comprises a main body, one or more inhalation valve attachments and a nasal pillow. In some embodiments, the nasal pillow is a U-shaped nasal pillow with modified openings. In some embodiments, the main body has three port openings in fluid communication with the pressure-relief safety mechanism, other generated therapies (which may be external) and the U-shaped nasal pillow. In some embodiments, the other generated therapies are delivered into the main body by way of waveguides, pipes, tubes, adapters or other transmission conduits. In some embodiments, the transmission conduit can be constructed using bio-compatible materials.

In some embodiments, the inhalation valve attachments are in fluidic communication with the main body of the nasal interface and optionally with the port openings. In some embodiments, the inhalation valve attachments consist of one-way valves that only open during inhalation, but close upon exhalation thereby redirecting the fluidic flow to the pressure-relief safety mechanism and/or to the externally generated therapies.

In some embodiments, the interconnections of the pressure-relief safety mechanism port opening and the externally generated therapy port opening are designed to be interchangeable to advantageously enable the use of either nostril. Advantageously, this interchangeable configuration overcomes the loss of therapy due to the nasal cycle phenomenon: a regular alternating partial congestion and decongestion of the nasal cavities in humans and other animals driven by the selective activation of one-half of the autonomic nervous system. It is understood that the nasal cycle is an alternation in both times and between left and right nostrils, wherein the net resistance remains unchanged. In some embodiments, the base of the U-shaped nasal pillow is configured to attach to the main body of the nasal interface. In some embodiments, the U-shaped nasal pillow consists of two tips, one for each nostril. In some embodiments, the tips are separated by a divider. In some embodiments, the tips are internally separated by a divider. In some embodiments, the tips are hollow, flared-out

and made from compressible biocompatible materials. In some embodiments, the tips sit inside the nostrils after insertion in a comfortable and nonabrasive manner. In some embodiments, the tips further consist of an orifice that allows for fluidic communication between the nostril and the nasal interface. In some embodiments, the orifice can be configured to different shapes and sizes such as, but not limited to circular, oval, elongated shapes, as well as small, medium, or large sizes to closely fit into the nostrils. In some embodiments, materials and methods used in fabrication of the said tips include blow-moulding, extrusion, casting and/or calendaring of biocompatible polymers such as, but not limited to polyurethanes, polyethylene (PE), polytetrafluoroethylene (PTFE) and polyethylene terephthalate (PET). The nasal interface shall be designed in a manner where access to the mouth and oral cavity is unobstructed throughout the entire therapy duration.

In some embodiments, the device as defined herein may further comprise a power transmitter or a power transmission mechanism. In some embodiments, the power transmitter is connected or coupled to the airflow obstruction mechanism to transmit the power from a motion generator to the airflow obstruction mechanism causing the motion of the components of the airflow obstruction mechanism. In some embodiments, the power transmitter is connected to a bottom casing of the airflow obstruction mechanism to transmit the power from a motion generator to the airflow obstruction mechanism causing rotation of the airflow obstruction mechanism. Accordingly, when assembled, the top casing and the bottom casing of the airflow obstruction mechanism may form a housing-like structure.

In some embodiments, the power transmission mechanism is in mechanical communication with the airflow obstruction mechanism or motion generation mechanism. In some embodiments, the power transmission mechanism is in mechanical communication with the airflow obstruction mechanism and the motion generation mechanism. In some embodiments, the power transmission mechanism transmits a motion that may be linear, oscillatory or rotational motion created by the motion generation mechanism to the airflow obstruction mechanism. In some embodiments, the power transmission mechanism may comprise mechanisms such as, but not limited to, mechanical linkages, shafts, gears, adhesives, bonds and magnets. In some embodiments, the power transmission mechanism or the motion generation mechanism may optionally be encased within the housing as described above. In some embodiments, the power transmission mechanism or the motion generation mechanism is disposed on the exterior of the housing or external to the housing module but still maintains fluidic and mechanical communication with the airflow obstruction mechanism. In some

embodiments, the power transmission mechanism is designed in a manner such that fluids including biofluids are unable to encounter the motion generation mechanism via inhalation, exhalation, expectoration, sternutation, and emesis.

5 In an exemplary embodiment, the bottom casing of the airflow obstruction mechanism may be connected to the power transmitter via a connecting means. In some embodiments, the connecting means may comprise a magnet array disposed between the housing and the bottom casing. In such an embodiment, a second magnet array having attraction forces towards the first magnet array may be disposed at the power transmitter to connect the same to the airflow obstruction mechanism. In some embodiments, the motion generation mechanism or the power
10 transmitter and the airflow obstruction mechanism may be physically separated by the housing module while still maintaining mechanical communication by means of said arrays of magnets.

In some embodiments, said bottom casing may comprise a second connector to connect the airflow obstruction mechanism to the airflow resistance mechanism. In such an embodiment, the airflow outlet may be positioned at the perimeter of the second connector to
15 partially direct the exhalation airflow from the device into the atmosphere.

In some embodiments, the motion generation mechanism may be an oscillatory or rotational generation mechanism that creates an oscillatory or rotational motion, which in turn, generates variable nasal PEP and/or O-PEP waveforms when coupled with the airflow obstruction mechanism, the power transmission mechanism, and the airflow resistance
20 mechanism. In some embodiments, the variable nasal O-PEP waveforms may be sinusoidal, square, and/or any form of pulsing in nature. In some embodiments, the motion generation mechanism is configured to operate with frequencies ranging from about 3 Hz to about 200 Hz for example 3 Hz, 4 Hz, 5 Hz, 6 Hz, 8 Hz, 10 Hz, 15 Hz, 20 Hz, 25 Hz, 30 Hz, 40 Hz, 50 Hz, 60 Hz, 70 Hz, 80 Hz, 90 Hz, 100 Hz, 120 Hz, 140 Hz, 150 Hz or 200 Hz. In some embodiments,
25 the frequencies may be in a range of from about 5 Hz to about 50 Hz. In some embodiments, the oscillatory or rotational generation mechanism creates these oscillatory or rotational motion by way of the following means, but not limited to a manual actuation via the use of gears, springs, levers, pulleys, bands, belts, pneumatics, hydraulics and/or magnets, powered actuation methods using electromechanical motion, powered hydraulics and/or powered
30 pneumatic motion or combinations thereof.

As previously described herein, in accordance with some embodiments, the airflow resistance mechanism may be in fluidic communication with the oscillatory or rotational airflow obstruction mechanism and the airflow outlet. In some embodiments, the airflow

resistance mechanism may be a variable or a constant airflow resistance mechanism. In some embodiments, the airflow resistance mechanism may comprise at least one component selected from the group consisting of one or a plurality of port, one or a plurality of flap, one or a plurality of fin, one or a plurality of vane, one or a plurality of disc, one or a plurality of rod and combinations thereof to provide a resistance to the airflow during exhalation. In some
 5 embodiments, each of the one or one of a plurality of port, one or a plurality of flap, one or a plurality of fin, one or a plurality of vane, one or a plurality of disc and one or a plurality of rod may comprise curved portion. In some embodiments, the airflow resistance mechanism may comprise screw threading or helical or worm gearing. In some embodiments, the airflow
 10 resistance mechanism, the oscillatory or rotational airflow obstruction mechanism and the airflow outlet are interconnected by a connecting means selected from the group consisting of waveguides, pipes, tubes, and adapters. It is to be understood that other suitable transmission conduits may also be used. In some embodiments, the connecting means or transmission conduits can be constructed using bio-compatible materials. In some embodiments, the variable
 15 airflow resistance mechanism coupled with the oscillatory or rotational airflow obstruction mechanism, power transmission mechanism and oscillatory or rotational generation mechanism advantageously all work in tandem to generate variable nasal PEP and/ or O-PEP waveforms.

In some embodiments, the variable nasal PEP or O-PEP waveforms are sinusoidal,
 20 square and/or any form of pulsing in nature, with frequencies in a range from about 3 Hz to about 200 Hz for example 3 Hz, 4 Hz, 5 Hz, 6 Hz, 8 Hz, 10 Hz, 15 Hz, 20 Hz, 25 Hz, 30 Hz, 40 Hz, 50 Hz, 60 Hz, 70 Hz, 80 Hz, 90 Hz, 100 Hz, 120 Hz, 140 Hz, 150 Hz or 200 Hz. In some embodiments, the frequencies may be in a range from about 5 Hz to about 50 Hz. The PEP including O-PEP waveforms are transmitted into the lungs via the airflow inlet and nasal
 25 interface that is in fluidic communication with the nostril. The PEP including O-PEP waveforms enable loosening and mobilization of the trapped sputum to the central airways for easy expectoration and/or swallowing. In some embodiments, pressure variation features are generated using one or a plurality of ports, one or a plurality of flaps, one or a plurality of fins, one or a plurality of vanes, one or a plurality of disks or any other combination of fluidic flow
 30 obstruction and/or disruption mechanisms during dynamic exhalation to generate variable nasal O-PEP waveforms. The pressure variation features may allow for the adjustment of pressure in the nasal cavity ranging from about 3 cmH₂O to about 50 cmH₂O, for example, 4 cmH₂O, 5 cmH₂O, 8 cmH₂O, 10 cmH₂O, 15 cmH₂O, 20 cmH₂O, 25 cmH₂O, 30 cmH₂O, 35 cmH₂O, 40

cmH₂O, or 45 cmH₂O, under standard conditions (temperature at 298.15K and pressure at 1 atm). In some embodiments, the pressure in the nasal cavity is in a range of $\geq$ about 5 cmH₂O to about 30 cmH₂O under standard conditions (temperature at 298.15K and pressure at 1 atm). In some embodiments, the pressure in the nasal cavity is about 5 cmH₂O under standard
5 conditions. In some embodiments, the pressure in the nasal cavity is greater than 5 cmH₂O under standard conditions.

The degree of fluidic flow resistance, which in turn affects the pressure during exhalation, can be varied as necessary. In some embodiments, the degree of fluidic flow resistance may be adjusted by any one of the followings: increasing or decreasing the number
10 of ports, flaps, fins, vanes, and disks; and/or changing the geometry of said ports, flaps, fins, vanes, and disks; and/or changing the material types. The variable airflow resistance mechanism is encased within the housing module and secured using mechanisms such as, but not limited to, snap-fits, threads, screws, adhesives, magnets, or any other forms of mechanical bonding. The controls of the variable airflow resistance mechanism are either disposed on the
15 housing module's exterior or external to the housing module. The controls of the variable airflow resistance mechanism shall be designed in a manner whereby mechanical communication is maintained with the variable airflow resistance mechanism encased within the housing module during inhalation and exhalation. The said controls utilize mechanisms such as, but are not limited to, mechanical linkages, shafts, gears, adhesives, bonds, and
20 magnets.

In some embodiments, said nasal PEP or O-PEP waveforms may be generated via an electrically powered DC motor coupled to a speed-control circuit. The shaft of the DC motor may be in mechanical connection with an oscillating or rotating disk. The oscillating or rotating disk may be in mechanical connection with the magnetic array that is part of the power
25 transmission mechanism.

In some embodiments, a barrier including a waterproof barrier may optionally be added to the device. Advantageously, the barrier may prevent the backflow of any generated biological fluids into the externally generated therapies.

In some embodiments, as mentioned above, the device disclosed herein further includes
30 the airflow outlet. In some embodiments, the airflow outlet is in fluidic communication with the airflow resistance mechanism including the variable airflow resistance mechanism. In some embodiments, the airflow outlet and the variable airflow resistance mechanism are

interconnected by way of waveguides, pipes, tubes, adapters, or other transmission conduits. In some embodiments, the conduits can be constructed using biocompatible materials. In some embodiments, the airflow outlet may be provided and thus functions as an orifice or channel that vents exhalation airflow out from the airflow resistance mechanism into the atmosphere.

5 In some embodiments, the device may further include securing or fixation means allowing the device to be handheld or worn on the patient's body in a hands-free manner. In addition to embossed features described for the nasal interface, fixation entities such as head, neck and/or ear straps are added to the device via any combinations of either the nasal interface, and/or housing and/or oscillatory/rotational generation mechanism to prevent slippage of the
10 device outside the nasal cavity during usage due to patient movement and/or gravity. In some embodiments, the fixation means includes but is not limited to the use of adhesives, uneven geometries or shapes and hooks to keep the device in place.

 In some embodiments, when the device disclosed herein is implemented, advantageously, access to the mouth and oral cavity is unobstructed throughout therapy
15 duration of 10 minutes to 60 minutes, for example 10 minutes, 15 minutes, 20 minutes, 30 minutes, 45 minutes and 60 minutes. Advantageously, the entire device, except the oscillatory/rotational generation mechanism, can be sterilized after each use and can be re-used. In some embodiments, the entire device or part thereof such as the nasal interface may be disposable. In some embodiments, the airway clearance device described herein is located
20 above the mouth thereby interfacing with the respiratory system intranasally. In some embodiments, the device described herein may be implemented in the form of an extra-nasal mask or an intra-nasal mask. In some embodiments, the device may have discretely located parts with or without an assembly body.

 In an exemplary embodiment, the device described herein comprises a nasal interface,
25 a pressure-relief safety mechanism, an oscillatory/rotational generation mechanism, a power transmission mechanism, an oscillatory/rotational airflow obstruction mechanism, a variable airflow resistance mechanism, securement installations, an airflow inlet, and an airflow outlet. In such an embodiment, the nasal interface, pressure-relief safety mechanism, oscillatory/rotational generation mechanism, oscillatory/rotational airflow obstruction
30 mechanism, variable airflow resistance mechanism, airflow inlet, and airflow outlet are in fluidic communication with each other. In some embodiments, the oscillatory/rotational mechanism, power transmission mechanism and oscillatory/rotational airflow obstruction

mechanism are in mechanical communication with each other. In some embodiments, the nasal interface, pressure-relief safety mechanism, oscillatory/rotational generation mechanism, power transmission mechanism, securement installations, airflow inlet, and airflow outlet can be configured in the following combinations: encased within the housing, and/or disposed on
5 the housing's exterior, and/or external to the housing but still maintaining fluidic and/or mechanical communication with the oscillatory/rotational airflow obstruction mechanism and the variable airflow resistance mechanism.

Advantageously, the device disclosed herein can interact in situ with other externally generated therapies during inhalation and exhalation through the nasal interface, which in turn
10 interacts with human body via the nostrils.

In some embodiments, the airway clearance device described herein is suitable for patients with moderate to severe obstructive lung diseases. In some embodiments, the device is also suitable for patients having chronic respiratory diseases. In some embodiments, the device disclosed herein is suitable for patients with moderate to severe obstructive lung
15 diseases lacking appropriate physical fitness and lung capacities. In some embodiments, the device is suitable for patients who constantly suffer from shortness of breath.

As mentioned herein above, the device disclosed herein is easy to use and operate. Further, unlike the commercially available airway clearance device, the device described herein requires minimal effort from the patient or may be considered effortless thereby resulting in
20 effective sputum clearance therapy.

The block diagrams illustrate architecture, functionality, or an operation of possible implementations of systems, methods, and computer program products according to various embodiments of the present disclosed subject matter. In this regard, each block in the flowchart or block diagrams may represent a module, segment, or portion of program code, which
25 comprises one or more executable instructions for implementing the specified logical function(s). It should also be noted that, in some alternative implementations, illustrated or described operations may occur in a different order or in combination or as concurrent operations instead of sequential operations to achieve the same or equivalent effect.

The corresponding structures, materials, acts, and equivalents of all means or step plus
30 function elements in the claims below are intended to include any structure, material, or act for performing the function in combination with other claimed elements as specifically claimed. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms

as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprising", "including" and/or "having" and other conjugations of these terms, when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other
5 features, integers, steps, operations, elements, components, and/or groups thereof.

The terminology used herein should not be understood as limiting, unless otherwise specified, and is for the purpose of describing embodiments only and is not intended to be limiting of the disclosed subject matter. While certain embodiments of the disclosed subject matter have been illustrated and described, it will be clear that the disclosure is not limited to
10 the embodiments described herein. Numerous modifications, changes, variations, substitutions and equivalents are not precluded.

It will be appreciated by a person skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined by the claims, which follow.

15

CLAIMS

1. An airway clearance device comprising:
an airflow inlet to guide the direction of airflow to the device during exhalation; and
an airflow obstruction mechanism, configured to receive the airflow from the airflow
5 inlet and to generate a positive expiratory pressure (PEP) via a cavity of a respiratory
conducting passage in a subject, wherein the airflow obstruction mechanism comprises an
airflow outlet.
2. The device according to claim 1, further comprising an airflow resistance mechanism
10 in fluid communication with the airflow outlet and the airflow obstruction mechanism, wherein
said airflow obstruction mechanism and airflow resistance mechanism are configured to
generate the PEP via the cavity of the respiratory conducting passage.
3. The device according to claim 1 or 2, wherein the PEP is an oscillatory PEP (O-PEP).
15
4. The device according to any one of claims 1 to 3, wherein said airflow obstruction
mechanism is actuated by a mechanical means or an electromechanical means causing motion
of the airflow obstruction mechanism.
- 20 5. The device according to claim 4, wherein when said airflow obstruction mechanism is
actuated by the electromechanical means, the device further comprising a power transmitter
configured to transmit the power from a motion generator to the airflow obstruction mechanism
causing motion of the airflow obstruction mechanism.
- 25 6. The device according to claim 4, wherein said mechanical means is selected from the
group consisting of crank gear and spring.
7. The device according to claim 4, wherein said motion is a linear motion or a rotating
motion.
30
8. The device according to claim 5, wherein said motion generator is an oscillatory
generator, configured to create an oscillatory motion thereby generating the PEP.

9. The device according to claim 5, wherein said motion generator is configured to operate with a frequency in a range from 0.5 Hz to 200 Hz.

5 10. The device according to any one of claims 1-9, wherein said airflow obstruction mechanism comprising at least one component selected from the group consisting of one or a plurality of port, one or a plurality of flap, one or a plurality of fin, one or a plurality of vane, one or a plurality of disc, one or a plurality of rod and combinations thereof to obstruct the airflow during exhalation.

10 11. The device according to claim 10, wherein the at least one component is disposed radially or axially relative to the vertical axis positioned at the centre of the airflow obstruction mechanism.

15 12. The device according to any one of claims 1 to 11, wherein the at least one of the airflow inlet, the airflow obstruction mechanism, the airflow resistance mechanism and the airflow outlet is enclosed within a housing.

13. The device according to claim 5, wherein the airflow obstruction mechanism is connected to the power transmitter via a connecting means.

20

14. The device according to claim 13, wherein the connecting means comprising a magnet array disposed at the outer surface of the housing.

25 15. The device according to any one of claims 10 to 14, wherein said one or one of a plurality of port, one or one of a plurality of flap, one or one of a plurality of fin, one or one of a plurality of vane, one or one of a plurality of disc and one or a plurality of rod comprising curved portion.

30 16. The device according to any one of claims 1 to 15, wherein said airflow resistance mechanism comprising at least one component selected from the group consisting of one or a plurality of port, one or a plurality of flap, one or a plurality of fin, one or a plurality of vane, one or a plurality of disc, one or a plurality of rod and combinations thereof to provide a resistance to the airflow during exhalation.

17. The device according to any one of claims 1 to 16, wherein the PEP generated is transmitted into the airway via a nasal interface.
- 5 18. The device according to any one of claims 1 to 17, wherein said device further comprising a pressure relief mechanism to vent excess pressure in the device higher than a threshold value, said pressure relief mechanism connecting the nasal interface and the airflow inlet.
- 10 19. The device according to claim 18, wherein said threshold value is up to 60 cm H₂O.
20. A system comprising the airway clearance device according to claim 1.
21. A method for clearing airway in a subject, said method comprising:
15 providing the airway clearance device according to claim 1;
 introducing air generated during exhalation to the device via the airflow inlet;
 generating a positive expiratory pressure (PEP) in the device; and
 transmitting generated PEP via a cavity of a respiratory conducting passage in
 the subject.
20
22. The method according to claim 21, wherein pressure within the cavity is adjustable from 5 to 50 cmH₂O at standard conditions.
23. The method according to claim 21 or 22, wherein the PEP generated has a volumetric
25 flowrate in a range from 6 L/min to 100 L/min under at-rest physiological breathing.
24. The method according to claim 21, wherein the PEP is an oscillatory PEP (O-PEP).