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(54) Title: MEDICAL DEVICE FOR IMPROVING AIRWAY PATENCY

FIG. 1

(57) Abstract: The present invention relates to
amedical device (10) for improving airway
patency of a patient's upper airway (14), com-
prising a sensor unit (40) configured to measure
at least one parameter indicative of a decreased
airway patency, in particular as a result of an ob-
structive sleep apnea incident,a stimulator unit
(44) configured to stimulate mechanoreceptors
(32) in the patient's upper airway to invoke the
central nerve system (30) of the patient, and a
control unit (42) for controlling the stimulator
unit(44)based on the at least one parameter re-
ceived from the sensor unit(40).

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Medical device for improving airway patency

FIELD OF THE INVENTION

The present invention relates to a medical device and a corresponding method for improving patency of a patient's upper airway, in particular for the treatment of sleep disorders caused by an obstruction or partial obstruction of the upper airway.

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BACKGROUND OF THE INVENTION

Obstructive Sleep Apnea (OSA) refers to a sleep disorder usually caused by an obstruction or partial obstruction of the upper airway and a restriction of the air passage into the lungs. It is characterized by repetitive pauses in breathing or instances of shallow and

10   infrequent breathing during sleep and it is usually associated with a reduction in blood oxygen saturation. Such pauses in breathing, lasting for more than 10 seconds are called apneas, typically last 20 to 40 seconds. Less severe but also often causing a decreased amount of air movement into the lungs and a drop in oxygen level in the blood are episodes of overly shallow breathing, called hypopnea. The obstruction of the upper airway is usually

15   caused by reduced muscle tonus in the upper airway that occurs during sleep. The human airway is composed of walls of soft tissue which can collapse and thereby obstruct breathing during sleep. Tongue tissue moves posteriorly towards the back of the throat during sleep and thereby blocks the air passages. OSA is therefore commonly accompanied by snoring.

Different invasive and non-invasive treatments for OSA are known. One of the

20   most powerful non-invasive treatments is the usage of continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) in which the patient uses a machine (CPAP machine or BiPAP machine) that blows cleaned air, oxygen or any modification thereof in a pressurized way through the airway of the patient in order to keep it open. Wearing a CPAP mask on a regular basis, however, becomes a burden for someone with

25   permanent OSA issues, and hence lacks patients' acceptance.

Then again, there are several invasive treatments of OSA which usually involve the use of implants for electrically stimulating selected nerves or muscle fibers to overcome the obstruction of the upper airway. A promising approach, for instance, is to electrically stimulate the muscle fibers of the genioglossus muscle. The genioglossus is the

muscle that runs from the chin to the tongue and is responsible for protruding the tongue. An active stimulation of this muscle forces the tongue into shape, and thus unblocks the upper airway. Alternatively, the hypoglossal nerve can be electrically stimulated using hypoglossal nerve stimulators (HGNS) to achieve the same effect.

5   Both approaches require electrodes to be implanted in target tissue either near the muscle fibers or near the hypoglossal nerve to apply a stimulus in form of a voltage or current signal. The stimulus needs to be applied directly to the selected nerve or muscle fibers and aims to overrule any signals sent from the central nerve system. Current implementation methods require accurate and selective stimulation of the target tissue, and thus a very precise

10   placing of the electrodes.

US 2010/0198103 A1 discloses a system and method for identify an optimal location on the target tissue, and placing an implant at such location to achieve optimal stimulation of such target tissue. In principal, the method describes a trial-and-error approach for finding a preferred target tissue by applying a stimulus on a first tissue and measuring the

15   results on a second tissue. If the desired response is not obtained, the electrode is repositioned until an optimal position is found.

A disadvantage of the aforementioned stimulation methods is that only selected muscles are stimulated. OSA, however, is a multifactorial disease with multiple anatomical structures involved, and thus with multiple muscle that need to be stimulated in

20   order to achieve efficient patency in the upper airway. Consequently, multiple electrodes have to be implanted to achieve the desired result. Additionally, the muscles that need to be activated might differ from one patient to the other, and therefore have to be determined for each patient individually. Thus, the treatment of OSA according to the known approaches is complex and error-prone. Hence, there is a need for an improved device and method.

25   WO 2013/113023 A1 discloses methods and systems for monitoring, preventing and/or treating upper airway disorders such as apnea, dysphagia, reflux and/or snoring. Upper airway disorders are prevented and/or treated by delivering one or more stimulations to one or more reflex-related afferents, efferents, muscles, and sensory receptors to manipulate the threshold and/or trigger an upper airway reflex. The mechanical stimulation

30   entails delivery of an amount of a liquid of relatively low viscosity such as water or saline, to the oral, nasal, or pharyngeal cavity of the subject.

WO 2012/134505 A1 discloses further systems and methods for treating apnea by controlled delivery of a swallow stimulus to a subject in which apnea is detected. In the systems and method, burst electrical or mechanical stimulation to one or more swallow-

related nerves and/or muscles can be timed for delivery between the expiration phase of the respiration cycle, following detection of an apneic event in the subject. A mechanical stimulation delivery device is configured for positioning adjacent to at least one swallow-related sensory receptor in the skin or mucosa of the subject, wherein the stimulation module is configured to generate mechanical stimulation. The mechanical stimulation delivery device comprises a device configured for delivery of a liquid to the oral, nasal, or pharyngeal cavity of the subject.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an alternative system for an unobtrusive treatment of a decreased patency of a patient's upper airway that is more efficient, less complex, and avoids the above mentioned disadvantages. Furthermore, a corresponding method shall be provided.

In a first aspect of the present invention a medical device for improving patency of a patient's upper airway is presented comprising:

- a sensor unit configured to measure at least one parameter indicative of a decreased airway patency, in particular as a result of an obstructive sleep apnea incident,

- a stimulator unit configured to stimulate mechanoreceptors in the patient's upper airway to invoke the central nerve system of the patient, and

- a control unit for controlling the stimulator unit based on the at least one parameter received from the sensor unit,

wherein the stimulator unit comprises an actuator for generating pressure pulses for invoking the mechanoreceptors, wherein the actuator comprises a piezo element activated in a pulsed manner, a piezoelectric micromachined ultrasonic transducer (PMUT), and/or a capacitive micromachined ultrasonic transducer (CMUT).

In a further aspect of the present invention a method is provided for improving patency of a patient's upper airway comprising the steps:

- receiving at least one parameter indicative of a decreased airway patency, in particular as a result of an obstructive sleep apnea incident, from a sensor unit;

- processing the measured parameter by a control unit,

- providing signals by the control unit to a stimulator unit for stimulating mechanoreceptors in the patient's upper airway to invoke the central nerve system of the patient, and

-       activating an actuator for generating pressure pulses for invoking the mechanoreceptors, wherein the actuator comprises a piezo element that is activated in a pulsed manner, a piezoelectric micromachined ultrasonic transducer (PMUT), and/or a capacitive micromachined ultrasonic transducer (CMUT).

Preferred embodiments of the invention are defined in the dependent claims. It shall be understood that the claim method has similar and/or identical preferred embodiments as the claimed device and as defined in the dependent claims.

According to the present invention a holistic approach to improve patency of the upper airway is used, since it has been found that multiple anatomical structures contribute to a collapse of the upper airway. While most of the known prior art documents like US 2010/0198103 A1 propose to directly stimulate selected targets (e.g. nerves or muscles), the present invention proposes to indirectly affect these targets by stimulating receptors of the central nerve system. The receptors are mechanoreceptors located, for instance, in the tongue base surface and respond to pressure by sending an afferent neuron signal to the central nerve system.

OSA patients have generally a higher airway resistance due to a narrow airway or other anatomical abnormalities. The high airway resistance leads to a higher pressure drop in the airway during inspiration which during wakefulness of the OSA patient is sensed by the mechanoreceptors and signaled to the central nerve system. As response, the central nerve system takes measures to compensate the high airway resistance, for instance, by increasing the muscle tonus of the tongue. The concrete measure chosen depends predominantly on the central nerve system and might differ from one patient to another. It is assumed that the central nerve system choses the right measures when a high airway resistance is indicated.

Studies have shown that for OSA patients the sensitivity of the mechanoreceptors decreases during the night. The threshold before a mechanoreceptor sends an afferent signal is higher then during the day, so that in sleep the airway of the OSA patient might collapses before the mechanoreceptors can indicate a shortfall to the central nerve system.

Hence, the proposed medical device determines at least one parameter indicative of a decreased airway patency via a sensor unit and supplementary stimulates the mechanoreceptors to indicate to the central nerve system the decreased air movement through the upper airway. Said parameter might be indicative of the muscle tonus of the tongue, the current pressure in the upper airway, the airflow into the patient's upper airway or the physical position of the anatomical structures involved in a collapse of the upper airway.

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Beyond that, any other internal or external measurable parameter indicative of an OSA event might be used as input to the device.

The proposed medical device further comprises of a control unit which takes the one or more parameter from the sensor unit as input and determines the presence of a decreased upper airway patency. Preferably, the control unit is a programmable integrated controller, for instance, a microcontroller with one or more inputs, an analog/digital converter, a processing unit, and programmable outputs. The assessment of the parameters is, preferably, based on predefined thresholds. If a specific parameter exceeds or falls below a predefined threshold, the outputs of the control unit are triggered which activate a corresponding stimulator unit.

The stimulator unit of the proposed device is configured to invoke the central nerve system by stimulating mechanoreceptors which are located in the tongue surface and at the epiglottis. The supplementary stimuli are invoked if the mechanoreceptors due to a lowered sensitivity fail to indicate the decreased air movement in the upper airway. In response to the supplementary stimuli from the stimulator unit the central nerve system sends control messages in form of an efferent neuron signal to specific targets to activate the body's natural mechanisms to react on the decreased air movement in the upper airway. One reaction could be, for instance, an increased muscle tonus of the tongue or other muscle activities which lead to a stabilization of the pharynx's walls. The reactions, however, are not limited to certain muscle activities in the upper airway but might affect other parts of the body as well. The decision how to react and what targets need to be affected depends solely on the central nerve system.

Thus, in contrast to systems known from prior art documents the present invention proposes to keep the central nerve system in control of activating the desired targets, since only the incoming signals (afferent neurons) to the central nerve system are stimulated while the outgoing signals (efferent neurons) from the central nerve system remain untouched. By shifting the responsibility of choosing the right measures to the central nerve system an easier, natural, and more efficient treatment of a decreased upper airway patency is achieved.

The stimulator unit comprises an actuator for generating pressure pulses to invoke pressure sensitive neurons (mechanoreceptors) in the upper airway. This actuator comprises at least one of a piezo-element, a piezoelectric micromachined ultrasonic transducer (PMUT), and a capacitive micromachined ultrasonic transducer (CMUT).

A piezo-element is an element, preferably a crystal, which is deformed when an external voltage is applied to it. It generates a mechanical movement which can be used to create air pulses in a manner similar to a loudspeaker or pulses in tissue by local displacement of the tissue. Subsequently, both means apply pressure on the mechanoreceptors. The piezo-element is activated in a pulsed manner to generate shock waves which impose sufficient pressure upon the mechanoreceptors to respond.

Further alternatives to the usage of a piezo element are piezoelectric micromachined ultrasonic transducers (PMUTs) and capacitive micromachined ultrasonic transducers (CMUTs). Micromachined ultrasonic transducers (MUTs) are fabricated in two design approaches, one using a semiconductor layer with piezoelectric properties (PMUTs) and another using a diaphragm and substrate with electrode plates that exhibit a capacitive effect (CMUTs).

PMUTs are MEMS-based piezoelectric ultrasonic transducers. Unlike bulk piezoelectric transducers which use the thickness-mode motion of a plate of piezoelectric ceramic such as PZT or single-crystal PMN-PT, PMUTs are based on the flexural motion of a thin membrane coupled with a thin piezoelectric film. In comparison with bulk piezoelectric ultrasound transducers, PMUTs can offer advantages such as increased bandwidth, flexible geometries, natural acoustic impedance match with water, reduced voltage requirements, mixing of different resonant frequencies and potential for integration with supporting electronic circuits especially for miniaturized high frequency applications.

CMUTs are tiny diaphragm-like devices with electrodes that convert the sound vibration of a received ultrasound signal into a modulated capacitance. For transmission the capacitive charge applied to the electrodes is modulated to vibrate the diaphragm of the device and thereby transmit a sound wave/pressure pulse. Since these devices are manufactured by semiconductor processes, the devices generally have dimensions in the 10-200 micron range, but can range up to device diameters of 300-500 microns. Many such individual CMUTs can be connected together and operated in unison as a single actuator.

Such recently developed ultrasound transducers may be used according to the present invention for generating pressure pulses for invoking the mechanoreceptors. Compared to their usual implementation in medical ultrasound imaging systems, they have to be only slightly modified, such that the sound waves transmitted by the transducers are used to invoke the mechanoreceptors. The possibility of receiving ultrasound signals and converting them for imaging applications is not necessarily needed in the present case. In other words, the CMUTs and PMUTs are herein preferably used as actuators, but not as

sensors. However, generally they could also be used as sensors, e.g. for detecting an apnea event.

According to an embodiment of the invention, the stimulator unit comprises a mechanical stimulating element for mechanically stimulating the mechanoreceptors to invoke an afferent neuronal signal to the central nerve system. In this case the mechanoreceptors are stimulated mechanically using a mechanical stimulating element. While mechanoreceptors might also be stimulated electrically, this embodiment has the advantage that a mechanical stimulation requires less energy if more than one mechanoreceptor has to be triggered. In particular, it does not require electrodes implanted in the target tissue to stimulate the mechanoreceptors. Additionally, a mechanical stimulation has the further advantage that only the afferent mechanoreceptor neurons are stimulated, since no efferent neuron response to a mechanical stimulation. An electrical stimulation might have the disadvantage that efferent neurons are unintentionally stimulated as well.

According to a further embodiment of the invention, the stimulator unit comprises an electrode for placement on or in the vicinity of the mechanoreceptors in the tongue, wherein the electrode is configured to stimulate the mechanoreceptors electronically. In this case the stimulator unit uses electrodes preferably in addition to the mechanical stimulating element to stimulate the mechanoreceptors. While stimulating via implanted electrodes is useful for a precise and selective activation of certain mechanoreceptors, the use of a mechanical stimulating element is more efficient when more mechanoreceptors at once have to be stimulated. Using both means, a mechanical stimulating element and an electrode, ensures an efficient as well as a selective activation of mechanoreceptors.

According to a further embodiment of the invention, the stimulator unit is implantable to the tongue base surface. Using an implant generally requires only a single surgery in which the device is implanted. After that the patient usually takes no further notice of the implant. The process of implanting a device is well-proven and established. In particular, implanting a device to the tongue base is relatively easy, since the tongue base is in general easily accessible. Using an implant is more comfortable for a patient, in particular if it provides for a long-term solution.

According to an alternative embodiment, the stimulator unit is arranged on an external device, in particular on or in a dental device. For example, the stimulator unit could be integrated in a dental device that is worn during the night. However, it is also conceivable that the whole device (also including the sensor unit and the control unit) is integrated into such a dental device. This way no surgery for implanting the device into the patient's body

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would be necessary. An integration of the device in a dental device could also be used during a test phase prior to implanting the final device into the patient's body.

According to a further embodiment of the invention, the sensor unit comprises an electromyography (EMG) sensor configured to measure a muscle tonus within the patient's upper airway, in particular the muscle tonus of the tongue, the palate and/or the pharynx muscle and/or a pressure sensor configured to measure the pressure in the upper airway. Electromyography (EMG) is a technique for evaluating and recording the electrical activity produced by a muscle. An EMG sensor may comprise either a surface electrode or an intramuscular electrode. An intramuscular electrode generally involves a tiny needle containing two fine-wire electrodes, which are inserted directly into the muscle tissue. Electromyography allows for a very precise measurement of the muscle tonus of particular muscles. The muscle tonus, for instance of the tongue, is a very good indicator whether there is an obstruction of the upper airway, in particular, if combined with further parameters. One further parameter might be determined by a pressure sensor which determines the current pressure or a pressure change in the upper airway. A pressure sensor acts as a transducer which generates an electrical signal as a function of the pressure imposed. Pressure sensors advantageously provide a non-invasive measurement of a parameter indicative of an obstruction of the upper airway. Both sensors types, EMG sensors and pressure sensors, may also be used in combination to provide multiple simultaneous measurements to determine an OSA event.

In a further embodiment, the sensor unit comprises at least one external sensor placed outside the patient's body. External sensors do not require any surgery and are thus particular easy to use. External sensors are the preferred choice if the device is only temporarily used. Additionally, external sensor may be used during a test phase for adjusting the internal sensor.

According to a further embodiment, the external sensor is arranged on or in a patient interface. Such a patient interface may comprise any of the following devices: a total face mask, a full face mask, a mouth mask, a nose mask or nasal inserts. Integrating parts of the device, e.g. the sensor unit, into such a patient interface has the advantage that both treatments, a generated pressurized flow of breathable gas and the herein proposed stimulation of the mechanoreceptors, can be applied in parallel. This may even more effectively treat OSA. It shall be noted that the stimulator unit and/or the control unit may also be arranged on or in a patient interface.

According to a further embodiment of the invention, the sensor unit comprises a flow meter that is configured to measure the airflow into the patient's upper airway. A flow meter is a device measuring the displacement of a gas or a liquid. The flow of air coming in through the mouth or nose into the patient's upper airway is a very good indicator to

5   determine whether the upper airway is blocked. Flow meters can easily be integrated into a patient interface, for instance, during a sleep study. The results of the sleep study can be used to adjust the internal sensor for a specific patient. The flow meter may, however, also be implanted in to the patient's upper airway together with the device.

In another embodiment of the invention, the sensor unit might be an image or

10   position sensor that is configured to detect changes in the anatomy of the upper airway. This image or position sensor may either be an external sensor or an implanted sensor. Since an OSA event is generally indicated by an abnormal positioning of the anatomical structures of the upper airway, a position sensor might be used to detect such an abnormal position. Measuring the change of position of anatomical structures can be done in various ways. A

15   non-limiting example would be the use of an accelerometer in the tongue to determine its change in position. Another position sensor might involve electrodes placed on the skin around the patient's chin to determine a position change by means of a varied skin tension. A further example is an optical position sensor which, for example, uses an optical actuator and detector. Furthermore, imaging sensors might be used to determine a movement of the

20   anatomical structures of the patient's upper way. An image sensor usually comprises a camera to obtain image data of the patient and an evaluation unit which determines based on the image data movements of the patient.

In a further preferred embodiment of the invention, the sensor unit is configured to communicate with one or more sensors and/or the control unit in a wireless

25   manner. Hence, no direct connection between the sensor and the control unit is required. The wireless data transmission is in particular advantageous for connecting external sensors to the control unit. A wireless interface at the control unit might as well be used for the programming and configuration of the device.

According to a further embodiment, the device comprises of a memory to store

30   a patient specific stimulation pattern, wherein the control unit is configured to activate the stimulator unit according to the specific stimulation pattern. In this case patient specific parameters might be stored in the memory such that the determination of an actual OSA event can be based on a patient specific profile. The stimulation pattern, for instance, might include individual thresholds at which the stimulator unit shall be activated. Furthermore,

patterns might be stored for an individual patient defining the frequency and/or intensity used to activate the stimulator. Preferably, such patient specific parameters are determined and validated during a sleep study.

According to a further embodiment of the invention, the device further comprises a power source outside the patient's body for transmitting power to the device in a wireless manner. Generally, a wireless power transmission is carried out using direct capacitive coupling or magnetic induction or by resonant magnetic induction. Wireless transmission is useful in cases where interconnecting wires are inconvenient, hazardous, or impossible. An external power source is in particular useful to charge an internal battery of the implanted device, so that the battery does not have to be changed physically, when it is discharged. The external power source itself could be battery powered and for instance integrated into a necklace worn by the patient whenever it is convenient for him.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiment(s) described hereinafter. In the following drawings

Fig. 1 shows an embodiment according to the present invention,

Fig. 2 shows a block diagram of an embodiment of a device according to the present invention,

Fig. 3a schematically illustrates a system according to prior art,

Fig. 3b schematically illustrates a mode of operation of an embodiment of the device according to the present invention,

Fig. 4 shows a block diagram of a preferred embodiment of the device according to the present invention, and

Fig. 5 shows a block diagram referring to an implementation of a method according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 shows a patient's head 12 from a side view, in particular the anatomy of the upper airway 14 of the patient. An embodiment of the new medical device is denoted with reference numeral 10. The upper airway 14 spans from the lips 16 through the pharynx 18 to the larynx opening 20. The dominant organ in the upper away 14 is the tongue 22. The genioglossus muscle 24 is one of the main muscles of the tongue which runs from the chin 26 into the tongue 22 and is responsible for protruding the tongue 22. OSA events are

characterized by a loss or reduction of the muscle tonus in the tongue 22, the palate 28 and/or

the pharynx 18 muscles. The muscle tonus is controlled by the central nerve system (CNS) 30

which activates the muscle fibers and forces them to tense. In an OSA event the CNS 30

controlled muscle activity, however, is too low to achieve a sufficient muscle tonus to keep

5   the airway open.

Furthermore, mechanoreceptors 32 are located at the tongue base surface 34

and at the epiglottis 36. Mechanoreceptors 32 are sensory receptors that respond to pressure

or distortion and sense the pressure in the upper airway 14. If the pressure falls below a

certain threshold the mechanoreceptors 32 send signals to the CNS 30. The CNS 30, in

10   response, increases via the hypoglossal nerve the muscle activity leading to a higher muscle

tonus which ultimately unblocks the upper airway 14. The process is known as

neuromuscular compensation and is carried out through the activity of afferent neurons,

interneurons, and efferent neurons as explained in greater detail below with reference to Figs.

3a and 3b. In principal, afferent neurons, interneurons, and efferent neurons form a closed

15   loop system of sensation, decision, and reactions.

For OSA patients the neuromuscular compensation is unbalanced. OSA

patients are often characterized by a higher muscle tonus compared to non-OSA subjects

while not asleep. Due to a narrow airway and/or an anatomical abnormality the airway

resistance of an OSA patient is generally higher. The airway resistance leads to a higher

20   pressure drop in the airway during inspiration. The mechanoreceptors 32 sense the negative

pressure and signal it via the afferent neurons to the CNS 30 (interneurons), which in

response increases the activity of the efferent neurons in order to increase the muscle tonus.

The stronger stimulation of the airway muscles by the efferent neurons increases

subsequently the patency of the upper airway 14. However, when asleep (or as a result of

25   sedative drugs) the sensitivity of the mechanoreceptors 32 decreases and the neuromuscular

compensation fails such that the upper airway 14 already collapses before the negative

pressure has been detected by the mechanoreceptors 32.

The new medical device 10 is a small electronic device that is preferably

implanted into the tongue base surface 34 of the patient's upper airway 14 and is capable of

30   stimulating the mechanoreceptors 32, and thus influencing the afferent neuron signal to the

CNS 30. The essential advantage of a stimulation of the mechanoreceptors 32 (afferent

neurons) is that the CNS 30 remains in control over the airway muscles and is thus able to

activate all muscle fibers that contribute to the neuromuscular compensation to achieve

patency of the upper airway 14. This includes the genioglossus muscle 24 to advance the

tongue base; the soft palate muscle fiber to stiffen and elevate the soft palate 28; and the muscle fibers in the pharynx wall 18 to counteract the transmural pressure on the pharynx wall 18.

Fig. 2 shows a block diagram of the medical device 10 shown in Fig. 1. The medical device 10 comprises a stimulator unit 44, a control unit 42, and a sensor unit 40, preferably, embedded in a single monolithic device.

The sensor unit 40 comprises one or more sensors capable of detecting at least one parameter indicative of a decreased airway patency. The parameter could be a direct indicator such as a pressure change in the upper airway 14 or an indirect indicator such as a decreased muscle tonus of the tongue 22. Preferably, a combination of multiple sensors is used to determine the relevant parameter.

The control unit 42 receives the input form the sensor unit 40 and evaluates based on the measurement the current situation in the upper airway 14. Preferably, several indicators are assessed by the control unit 42 to finally determine a single score which is indicative of a decreased airway patency. If the score indicates a decreased patency, the control unit 42 will subsequently activate the stimulator unit 44.

The stimulator unit 44 stimulates the mechanoreceptors 32 which are located at the tongue base surface 34 and the epiglottis 36. In response, the mechanoreceptors 32 will invoke the central nerve system 30 which will initiate the necessary reaction to overcome the decreased patency. This reaction could be an increase of muscular activity in the upper airway 14 leading to a higher muscle tonus which ultimately unblocks the upper airway 14. The reactions, however, are not limited to certain muscle activities in the upper airway 14, but might affect other parts of the body as well. The decision how to react and what targets need to be affected depends solely on the central nerve system 30.

The reaction, however, will be more natural compared to a direct stimulation of muscle fibers, and thus more comfortable to the patient 12. Preferably, the patient 12 takes no notice of the activation of the stimulator unit and the reaction thereupon. Hence, the device is well suited to be used at night while the patient 12 is asleep.

With reference to Figs. 3a and 3b, the different operating modes of devices according to the prior art and according to the present invention are explained in more detail. Fig. 3a and 3b both schematically illustrate the control loop 46 of the autonomic nerve system of the human body. The control loop 46 comprises the central nerve system 30 with somatic sensors 48 on the input side I. The somatic sensors 48 comprise among others the

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previously mentioned mechanoreceptors 32. On the output side II the control loop 46 further comprises targets 50 which can be controlled by the CNS 30.

The somatic sensors 48 react on the sensations of touch, pressure, vibration, heat, cold, and/or pain and send thereupon a signal to the CNS 30. The signaling is done via afferent neurons 52 (otherwise known as sensory, receptor neurons, and afferent axons) that carry nerve impulses from the somatic sensors 48 towards the central nerve system 30.

Depending on the afferent neuron signal 52 the central nerve system 30 responds by sending messages to various targets 50 using efferent neurons 54. Efferent neurons 54 (otherwise known as motor or effector neurons) carry nerve impulses away from the CNS 30 to the targets 50. Hence, the efferent neuron signal 54 is the output of the central nerve system 30 controlling the muscle activities in the body. The targets 50 are therefore also called effectors and include muscles or glands.

Changes to the effectors, for instance an increased muscle tonus, will subsequently affect the somatic sensors 48 as depicted here by the link 56. The whole process is a "closed loop" system of sensation, decision, and reactions.

Fig. 3a shows a device 58 according to the prior art. The device 58 is designed to influence the output signal coming from the CNS 30 by "overruling" the efferent neuron signal 54. The prior art device 58 thus engages the output side II of the control loop 46. This is done by injecting a current into the tissue, and thus artificially activating the effectors. The prior art device 58 therefore takes control over certain effectors blocking any signals coming from the CNS 30. The effect is depicted in Fig. 3a by the disruption 60 of the connection between the CNS 30 and the targets 50. In fact, the disruption 60 is an overruling of the signals from the central nerve system 30 to the targets 50.

Fig. 3b in contrast illustrates how an embodiment of the new medical device 10 is implemented. In Fig. 3b the same control loop 46 with somatic sensors 48, the CNS 30, and targets 50 is shown as in Fig. 2a. The device 10 according to the present invention, however, engages the control loop 46 on the input side I, thus affecting the afferent neuron signal 52 as opposed to the efferent neuron signal 54 on the output side II. This way, the CNS 30 is not overruled and remains in full control over the output side II, and thus the response to the stimulation by the medical device 10. Preferably, the medical device 10 enhances the signals sent by the somatic sensors 48 in cases when the mechanoreceptors 32 fail to indicate a decreased air movement in the upper airway 14, for instance, due to a lowered sensitivity.

With reference to Fig. 4, a preferred embodiment of a device according to the present invention is shown. The medical device is in entirety denoted with reference numeral

10. The medical device 10 comprises a stimulator unit 44, a control unit 42, and a sensor unit 40.

The sensor unit 40 may comprise several individual sensors each connectable to the control unit 40, preferably, in a wireless manner. The sensors might be internal sensors integrated into the device or external sensors which can be connected to the device. The sensor unit 40 is configured to measure via the sensors at least one parameter indicative of a decreased air movement in the upper airway 14 of a patient 12. Such a parameter might be a decreased airflow into the upper airway 14 of a patient, an abnormal pressure within the upper airway 14, a decreased muscle tonus in the tongue 22, and/or an abnormal position of the anatomical structures of the upper airway 14. The sensors could thus include one or more electromyography (EMG) sensors 62, one or more pressure sensors 64, one or more flow meters 66 and/or one or more position sensors 68.

An EMG sensor 62 detects the electrical potential generated by muscle cells when these cells are electrically or neurologically activated, preferably via electrodes that are implanted near or on that specific muscle. Hence, the EMG sensor 62 is capable of determining the tonus of the muscles in the tongue 22 and/or the muscle located in the walls of the pharynx 18. If the tonus is as high as during episodes of stable breathing, the stimulator unit 44 will not be activated. However, if the tonus decreases below a certain threshold, the stimulator unit 44 will be activated to stimulate the mechanoreceptors 32. The certain threshold is a patient 12 specific value which can be validated during a sleep study.

The sensor unit 40 may further comprise a pressure sensor 64 which preferably acts as a transducer generating an electrical signal as a function of the pressure imposed. The pressure sensor 64 measures the ambient pressure in the upper airway 14, in particular during inspiration. The change in the ambient pressure can be further parameter indicative of a decreased patency of the upper airway 14.

The flow meter 66 is preferably an external sensor located outside the patient's body (Fig.1). In a preferred embodiment the flow meter 66 is arranged in a patient interface such as a full face mask, a mouth mask, a nasal mask, a nasal insert, or a mouthpiece as depicted in Fig. 1. The flow meter 66 might be a positive displacement meter measuring the volumetric flow rate of air into the upper airway 14 of the patient 12. If the airflow falls below a predefined threshold, the stimulator unit 44 is triggered accordingly.

A position sensors denoted with reference numeral 68 can be realized in various ways. A position sensor 68 can be an imaging device combined with an evaluation

unit to collect image data of the patient and to determine an abnormal positioning of the anatomical structures from the image data.

It shall be noted that the invention is not limited to the aforementioned sensor; the present invention includes any sensors capable of indicating an instance of an abnormal upper airway. It shall be also noted that one of the above-mentioned sensor types is sufficient for the function of the presented device 10. A combination of these sensor types might be preferred in some instances, but is not mandatory.

The parameters measured by the sensors of the sensor unit 40 are transferred to the control unit 42. The control unit 42 is preferably a microcontroller with digital and/or analogous inputs, a central processing unit 72, and digital and/or analogous outputs. In a preferred embodiment, the control unit 42 further comprises of a programmable memory 74 to store predefined thresholds and/or stimulating patterns.

The control unit 42, preferably, compares the incoming parameters with predefined threshold values stored in the memory 74. In other embodiments more sophisticated assessment functions may be utilize. If a decrease air movement is detected in the upper airway 14, i.e. one or more parameter exceeds or falls under a predefined threshold, the control unit 42 activates via the outputs the stimulator unit 44.

The stimulator unit 44 comprises at least of one stimulating element that is configured to stimulate mechanoreceptors located in the upper airway 14 of the patient 12. In a preferred embodiment the stimulating element is a mechanical stimulator element 76 implanted into the tongue base surface. Preferably, the mechanical stimulator element 76 comprises a piezo-element, a PMUT or a CMUT.

A piezo-element comprises of a solid material such as a crystal or a certain ceramic which is deformed if an electrical field is applied to it. In a preferred embodiment the piezo-element is stimulated in a pulsed manner causing a forced oscillation of the piezo-element. The oscillation, in return, generates small air pulses or a pulsed vibration of tissue which cause a local pressure change at the piezo-element in the upper airway 14 of the patient 12. These small air pulses or a pulsed vibration of tissue may be similarly generated by means of a PMUT or a CMUT. The local pressures change is detectable by the mechanoreceptors 32 located around the upper airway 14.

Mechanoreceptors 32 require on average an applied mean force of 0.15mN to respond. In a preferred embodiment, the piezo-element might have an active surface area of 1 mm^2, wherein the material used for the piezo-element generates a power per active surface area of 10mW/mm^2. If the piezo-element generates a shock wave with a ramping up slope of

1μm/μs the resulting force would be 10mN, and thus more than sufficient to activate the relevant mechanoreceptors 46.

Additionally, mechanoreceptors 32 may be triggered electronically as well. Hence, the stimulator unit 44 may further comprise an electrical stimulator element 78 with

5   electrodes implanted in tissue near the mechanoreceptors 32. By applying a voltage or current signal to the electrodes the mechanoreceptors 32 are invoked in a manner similar to a mechanical stimulation. An electrical stimulator element 78 allows for a more selective stimulation. However, electrical stimulation might unintentionally trigger efferent neurons as well. In a preferred embodiment, both mechanical 76 and electrical stimulator elements 78

10   are used jointly.

In a further preferred embodiment, the medical device 10 may comprise an external power source 80 (Fig. 1) which is arranged outside the body. The power source 80 is configured to transmit the necessary energy needed by the implanted device 10 via direct induction. The power source 80, for instance a battery powered transmitter, could be arranged

15   in a necklace worn by the patient 12. In yet another embodiment parts of the control unit 42 might be arranged outside the patient's body as well, in particular an on/off switch or a programming unit.

With reference to Fig. 5, the method according to the present invention is illustrated via a block diagram.

20   The first block 100 denotes the measuring of the at least one parameter indicative of a decreased airway patency. This includes a continuous determination of the desired parameters from multiple sensors.

In step 102 the measured parameters are processed. Preferably, the parameters are compared with predefined thresholds to determine whether the air movement in the upper

25   airway is decreased. If any of these parameters exceed or fall below a certain threshold the next step 104 is invoked.

Step 104 involves the stimulating of the mechanoreceptors to invoke the central nerve system. Preferably, the stimulation is done mechanically by applying pressure to the mechanoreceptors located in the tongue base surface. As a result of the stimulation the

30   central nerve system will take necessary measures to open up the upper airway, for instance, by a muscular stabilization of the airway. Any change to the airway will be detected by the sensor unit initiating a reassessment of the current situation. If sufficient patency of the upper airway is achieved, the stimulation will be stopped or decreased until a further shortfall of air

movement in the upper airway is detected. By adapting the evaluation function within step 102 the control loop can be adjusted and optimized.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive; the invention is not limited to the disclosed embodiments. Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims.

In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. A single element or other unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage.

Any reference signs in the claims should not be construed as limiting the scope.

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CLAIMS:

1.   Medical device (10) for improving airway patency of a patient's upper airway
(14), comprising:

        a sensor unit (40) configured to measure at least one parameter indicative of a
decreased airway patency,

5   a stimulator unit (44) configured to stimulate mechanoreceptors (32) in the
patient's upper airway to invoke the central nerve system (30) of the patient (12), and

        a control unit (42) for controlling the stimulator unit (44) based on the at least
one parameter received from the sensor unit (40),

        wherein the stimulator unit (44) comprises an actuator for generating pressure

10   pulses for invoking the mechanoreceptors (32), wherein the actuator comprises a piezo
element activated in a pulsed manner, a piezoelectric micromachined ultrasonic transducer
(PMUT), and/or a capacitive micromachined ultrasonic transducer (CMUT).
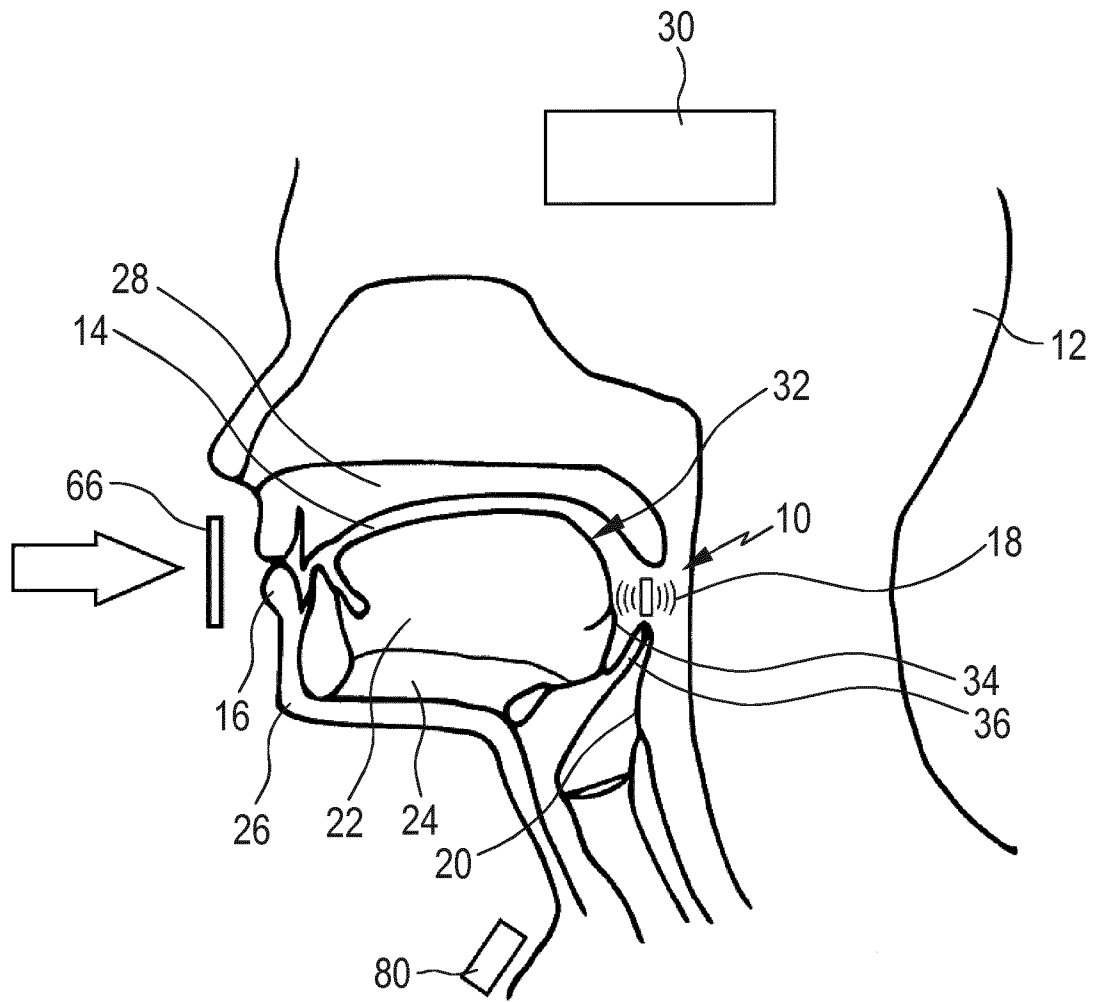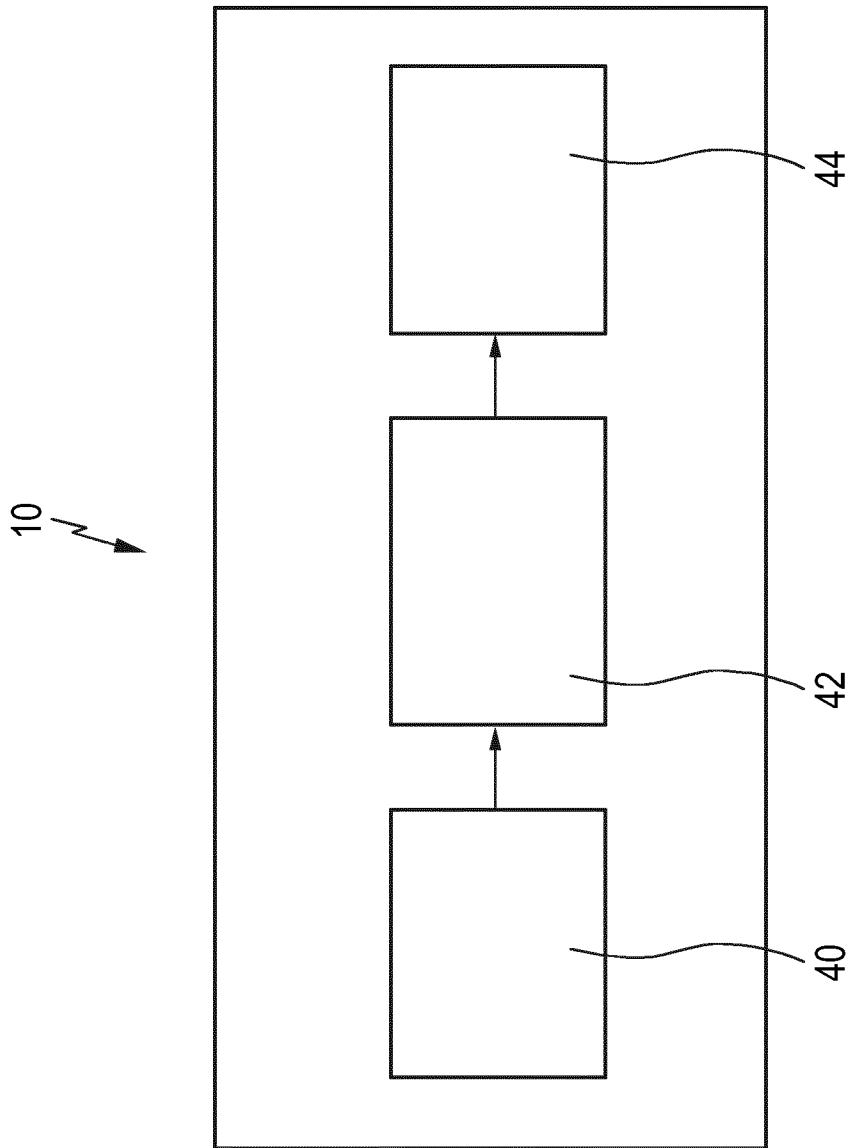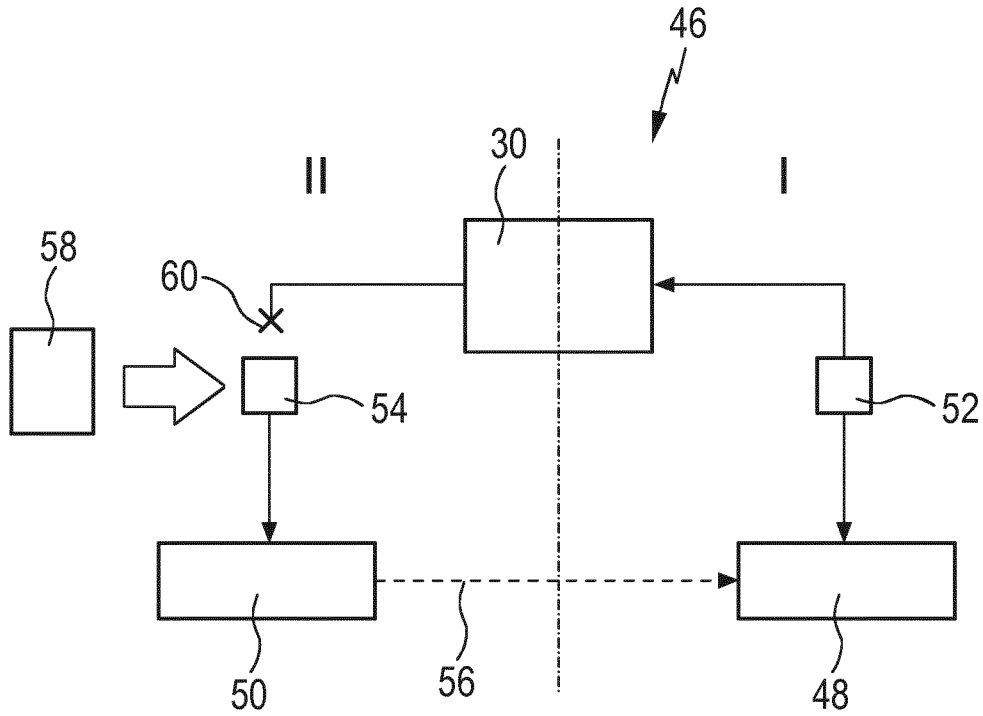
2.   Medical device according to claim 1, wherein the stimulator unit (44)

15   comprises a mechanical stimulating element (76) for mechanically stimulating the
mechanoreceptors (32) to invoke an afferent neuronal signal (54) to the central nerve system
(30).

3.   Medical device according to claim 2, wherein the stimulator unit (44)

20   comprises an electrode for placement on or in the vicinity of the mechanoreceptors (32),
wherein the electrode is configured to stimulate the mechanoreceptors (32) electronically.

4.   Medical device according to claim 1, wherein the stimulator unit (44) is
implantable to the tongue base surface (34).

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5.   Medical device according to claim 1, wherein the sensor unit (40) comprises
an electromyography (EMG) sensor (62) configured to measure a muscle tonus within the
patient's upper airway and/or a pressure sensor (64) configured to measure the pressure in the
upper airway (14).

6.   Medical device according to claim 1, wherein the sensor unit (40) comprises at least one external sensor placed outside the patient's body.

5   7.   Medical device according to claim 6, wherein the at least one external sensor is arranged on or in a patient interface.

8.   Medical device according to claim 1, wherein the sensor unit (40) comprises a flow meter (66) that is configured to measure the airflow into the patient's upper airway.

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9.   Medical device according to claim 1, wherein the sensor unit (40) comprises an image or position sensor (68) that is configured to detect changes in the anatomy of the upper airway (14).

15   10.   Medical device according to claim 1, wherein the sensor unit (40) is configured to communicate with one or more sensors and/or the control unit (42) in a wireless manner.

11.   Medical device according to claim 1, further comprising a memory (74) to
20   store a patient specific stimulation pattern, where in the control unit (42) is configured to activate the stimulator unit (44) according to the specific stimulation pattern.

12.   Medical device according to claim 1, wherein the device (10) further comprises a power source (80) outside the patient's body for transmitting power to the device
25   in a wireless manner.

13.   Method for improving airway patency of a patient's upper airway (14), comprising:
-          receiving at least one parameter indicative of a decreased airway patency from
30   a sensor unit (40),
-          processing the received parameter by a control unit (42),
-          providing signals by the control unit (42) to a stimulator unit (44) for stimulating mechanoreceptors (32) in the patient's upper airway (14) to invoke the central nerve system (30) of the patient based on the processed parameter, and

-         activating an actuator for generating pressure pulses for invoking the mechanoreceptors, wherein the actuator comprises a piezo element that is activated in a pulsed manner, a piezoelectric micromachined ultrasonic transducer (PMUT), and/or a capacitive micromachined ultrasonic transducer (CMUT).
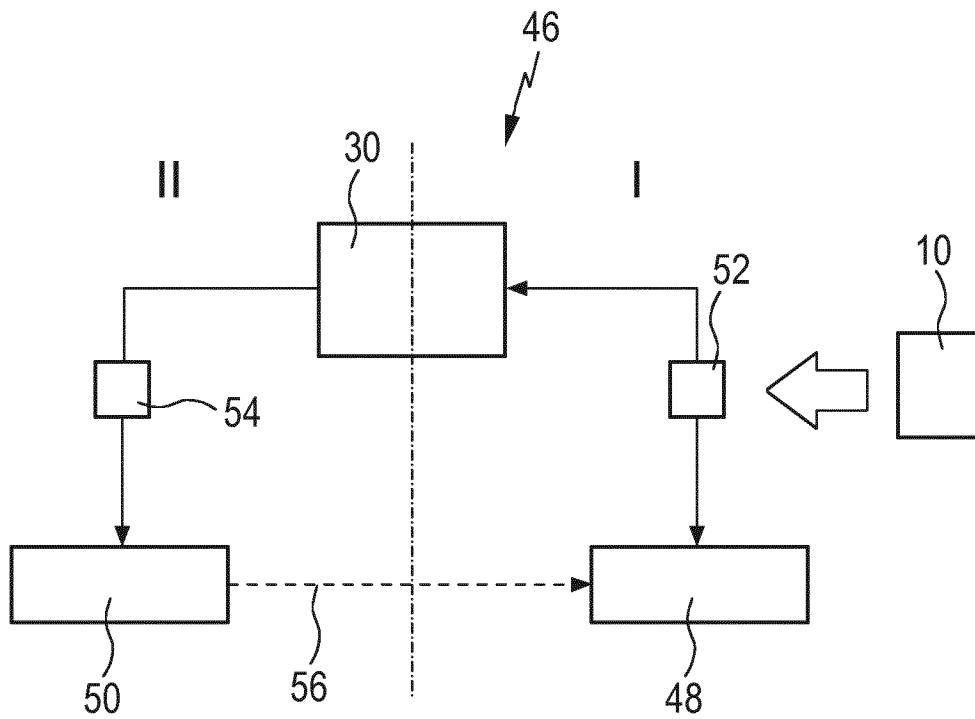
FIG. 1

FIG. 2

FIG. 3a

FIG. 3b

FIG. 4

5/5

FIG. 5

| Box No. II | Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet) |

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:   13
   because they relate to subject matter not required to be searched by this Authority, namely:

   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

| Box No. III | Observations where unity of invention is lacking (Continuation of item 3 of first sheet) |

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest
   [ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

   [ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

   [ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N1/36   A61F5/56   A61H23/02
ADD. A61B5/0488   A61H9/00   A61B5/08   A61B5/113   A61B5/00
      A61M16/00

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)

A61N   A61B   A61H   A61F   A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/079909 A1 (RESMED LTD [AU]; UJHAZY ANTHONY JOHN [AU]; BREWER GREGORY NEWTON [AU]) 1 September 2005 (2005-09-01)	1-10,12
Y	page 1, line 8 - line 9 page 3, line 7 - page 7, line 11 -----	11
A	US 2013/245505 A1 (KHURI-YAKUB BUTRUS T [US] ET AL) 19 September 2013 (2013-09-19) paragraph [0003] paragraph [0041] paragraph [0044] -----	1
Y	US 2002/049479 A1 (PITTS WALTER C [US]) 25 April 2002 (2002-04-25)	11
A	paragraph [0018] - paragraph [0028] -----	4,5
	-/--	

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

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 February 2015	27/02/2015

| Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016 | Authorized officer Ließmann, Frank |

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation).	DOCUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2013/113023 A1 (NEUROSTREAM TECHNOLOGIES G P [CA]; WILSON WILLARD [US]) 1 August 2013 (2013-08-01) the whole document -----	1-12
A	EP 2 460 475 A2 (UNIV WESTERN ONTARIO [CA]; MARTIN RUTH E [CA]; BIHARI FRANK [CA]; THEU) 6 June 2012 (2012-06-06) the whole document -----	1-12

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			US	2010152553 A1	17-06-2010
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US 2002049479	A1	25-04-2002	NONE		
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