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(71) **Demandeur/Applicant:**
GHUGE, RAGHAVENDRA VITTHALRAO, US

(72) **Inventeur/Inventor:**
GHUGE, RAGHAVENDRA VITTHALRAO, US

(74) **Agent:** GOWLING WLG (CANADA) LLP

(54) **Titre : DISPOSITIFS DE REPOSITIONNEMENT MANDIBULAIRE ET LINGUAL DYNAMIQUES, POSTE DE COMMANDE, ET PROCEDES DE TRAITEMENT ET/OU DE DIAGNOSTIC DE TROUBLES MEDICAUX**

(54) **Title: DYNAMIC MANDIBULAR AND LINGUAL REPOSITIONING DEVICES, CONTROLLER STATION, AND METHODS OF TREATING AND/OR DIAGNOSING MEDICAL DISORDERS**

(57) **Abrégé/Abstract:**
Mandibular lingual repositioning devices include a mandibular piece having a first teeth covering and a housing proximate a left molar portion and a right molar portion that each have a first drive and a protrusive flange extending cranially and a stimulator protrusion extending toward the tongue each extend from the housing, and include a maxillary piece having a second teeth covering and a housing proximate each of a left molar portion and a right molar portion that each have a second driver. Each housing encloses a power source electrically connected to a motor and to an on-board circuit board, and has its respective driver operatively connected to a respective motor. Each housing of the mandibular piece also has an electrode of a stimulator electrically connected to its power source. Each first driver is operatively engaged with the maxillary piece and each second driver is operatively engaged with a protrusive flange.

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Abstract:

Mandibular lingual repositioning devices include a mandibular piece having a first teeth covering and a housing proximate a left molar portion and a right molar portion that each have a first drive and a protrusive flange extending cranially and a stimulator protrusion extending toward the tongue each extend from the housing, and include a maxillary piece having a second teeth covering and a housing proximate each of a left molar portion and a right molar portion that each have a second driver. Each housing encloses a power source electrically connected to a motor and to an on-board circuit board, and has its respective driver operatively connected to a respective motor. Each housing of the mandibular piece also has an electrode of a stimulator electrically connected to its power source. Each first driver is operatively engaged with the maxillary piece and each second driver is operatively engaged with a protrusive flange.

DYNAMIC MANDIBULAR AND LINGUAL REPOSITIONING DEVICES, CONTROLLER STATION, AND METHODS OF TREATING AND/OR DIAGNOSING MEDICAL DISORDERS

TECHNICAL FIELD

[0001] This application relates to maxillary and/or a mandibular and lingual repositioning devices and methods of treating and/or diagnosing obstructive sleep apnea and other sleep disorders and/or medical conditions using the same, more particularly, to a maxillary and/or a mandibular and lingual repositioning device that can make protrusive movement and vertical movement of the jaw(s) and/or provide electrical impulse stimulation to the muscle of the soft pallet and hard pallet, and/or the lateral pterygoid muscles to move the lower jaw forward and/or move the tongue, simultaneously, sequentially, or independently.

BACKGROUND

[0002] Many individuals suffer from disordered breathing while asleep. Some example disorders include obstructive sleep apnea (OSA), snoring, snore arousals, sleep-related hypoxia, and other conditions dependent on, correlated with, and caused by snoring or OSA. OSA is a condition in which sleep is repeatedly interrupted by an inability to breathe, which is typically a results of intermittent obstruction of the airway by the tongue and a general relaxation of the muscles which stabilize the upper airway segment, which can cause a lack of oxygen, snoring, cardiovascular and neurological complications, such as sleep-induced hypertension, heart attacks, cardiac arrythmias, strokes, Alzheimer's disease, hypertension, sleep-induced hypertension, diabetes, weight gain, and depression to name a few.

[0003] Mandibular repositioning devices have been FDA-approved and used as a treatment for sleep apnea when treatment by a CPAP (Continuous Positive Airway Pressure) machine has been ineffective for the particular patient, or when a patient is unable to tolerate a PAP (Positive Airway Pressure) device. Most oral appliances on the market have only been able to control approximately 50% of sleep apnea events. There are a large number of patients that are intolerant to PAP devices, some due to the PAP device or the mask but most due to excessive high air pressure that may be medically recommended for keeping an open airway. Repeated adjustments have to be performed in attempts to make intolerant patients tolerate a PAP device, most of which require manual adjustments by a professional or require repeated sleep studies after a sleep study. Since a large number of patients with OSA have thus remained untreated due to various reasons, there is a serious need for a new method of treatment that can maintain an open airway during sleep using a combination of jaw stabilization and simultaneous advancement of the jaw and tongue, i.e., a dynamic mandibular and lingual repositioning device as disclosed herein.

[0004] There is also a need for such a device that can continuously learn (artificial intelligence) a particular person sleep-related breathing, blood pressure, heart rate and rhythm, body positioning, depth of sleep and oxygen levels, silent or symptomatic acid reflux during sleep and amount of bruxism (teeth grinding) over periods of days, months and even years while the person sleeps at

home or elsewhere, thereby removing the need of performing expensive sleep studies. While using such a device it should lend itself to continuously making automatic, guided, algorithmic (SERVO) adjustments to the treatment of these medical conditions and continuously providing information related to improvement in oxygen levels, breathing, blood pressure, heart rate and rhythm, acid reflux and bruxism and sleep depth, quantity and quality to the controller, cloud-based server system and to the treating physician, providing a lifelong (life of the device) safe open airway with reliable normalization of oxygen, breathing and sleep.

SUMMARY

[0005] In all aspects, mandibular repositioning devices are disclosed that have a maxillary piece with a tooth covering having a driver flange protruding laterally outward on a right side proximate a backmost teeth mold and/or on a left side proximate a backmost teeth mold and a mandibular piece with a tooth covering having a protrusive flange extending cranially therefrom positioned to have a posterior side engaged with the anterior side of each driver flange. Each driver flange has an anterior side with a convex curvature and each protrusive flange has a posterior side with a concave-to-convex curvature from its base toward its most cranial point. The posterior side of each protrusive flange has a convex portion of the concave-to convex curvature engaged with the convex curvature of the driver flange in a rest position. Downward movement of the mandibular piece moves the convex portion of the posterior side of the protrusive flange along the convex curvature of the driver flange, thereby moving a user's mandible forward. In all embodiment, the convex portion of the curvature of the protrusive flange can engage with the convex curvature of the driver flange at a point that is two thirds of the height of the driver flange

[0006] In all embodiments, the protrusive flange can be removably replaceably attached to the mandibular piece and/or the driver flange can be removably replaceably attached to the maxillary piece. The driver flange has a base that is positioned on the maxillary piece.

[0007] In all embodiments, the protrusive flange and the driver flange can be positioned to place an engagement point of the convex portion of the concave-to convex curvature with the convex curvature of the driver flange at a midpoint length that is at half the lineal distance from a vertical axis at the front of the incisors (incisor vertical axis) to a point on a parallel vertical axis aligned with the temporo-mandibular joint (TMJ) at rest (TMJ vertical axis). The majority of the convex curvature of the driver flange is defined by an arc having a center at a point on the TMJ vertical axis that is one third of the height of the driver flange measured from the horizontal dental axis and has a radius length equal to the midpoint length. The convex curvature of the driver flange has a back-cut most proximate a base of the driver flange. The back-cut portion is determined by an arc from a center point positioned on the TMJ vertical axis at two thirds of the height of the driver flange measured from the horizontal dental axis. A convex curvature of the convex portion of the protrusive flange is defined by an arc having a center at a point on the incisor vertical axis that is at two thirds the height of driver flange measured from the horizontal dental axis and has a radius length equal to the

midpoint length. A concave curvature of the concave portion of the protrusive flange is defined by an arc drawn from a point on the TMJ vertical axis that is one third of the height of the driver flange measured from the horizontal dental axis and has a radius length equal to the midpoint length.

[0008] In all embodiments, the anterior side of the protrusive flange has a convex curvature.

[0009] In another aspect, the mandibular repositioning devices have a maxillary piece that includes a housing proximate one or both of a left molar portion and a right molar portion, wherein each housing encloses a power source electrically connected to a motor and to an on-board circuit board and has a driver operatively connected to the motor and to the driver flange for anterior and posterior movements of the driver flange; and the mandibular piece has a housing proximate one or both of a left molar portion and a right molar portion and the mandibular device has a laterally inward extending protrusion extending from each housing toward the tongue at a position proximate a lingual muscle of the tongue, wherein each housing of the mandibular piece encloses a power source electrically connected to an on-board circuit board which is in electrical communication with one or more sensors enclosed within the laterally inward extending protrusion, or the maxillary piece has a palate housing portion and/or a buccal housing portion extending from each housing thereof and each palate housing portion and buccal housing portion encloses therein a power source electrically connected to an on-board circuit board which is in electrical communication with one or more sensors. The one or more sensors are selected from the group consisting of a pulse oxygen sensor, a vibration and airflow sensor, a pH sensor, a doppler ultrasound sensor, an M-Mode ultrasound sensor, a 2D ultrasound sensor, 3D ultrasound sensor, a pressure plate sensor for measuring bruxism, a pulse transit time sensor, EEG, EMG, EOG, lactic acid sensor, hygroscopic/hydration sensor, video and audio recording, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, and a cardiac trans-oral echocardiography sensor.

[0010] In one embodiment, when the mandibular piece houses the one or more sensors, each on-board circuit within housings of the maxillary piece include a receiver and a microprocessor having an instruction stored in nontransitory memory to activate each motor and each on-board circuit board within housings of the mandibular piece include a receiver, a transmitter, and a microprocessor having an instruction in nontransitory memory to activate each motor within housing of the maxillary piece simultaneously based on data received from the one or more sensors. In another embodiment, when the maxillary piece houses the one or more sensors, each on-board circuit within the housings of the maxillary piece include a microprocessor having an instruction in nontransitory memory to activate each motor simultaneously based on data received from the one or more sensors.

[0011] In another aspect, the mandibular repositioning devices have a mandibular piece that has a motor housed within each housing thereof and has a cranial-to-caudal driver operatively connected to each motor. The cranial-to-caudal driver is operatively engaged with the maxillary piece for cranial and caudal adjustment of the device from instructions stored in the nontransitory memory of the on-

board circuit board within each housing of the mandibular piece based on data received from the one or more sensors. In some embodiments, one or both of the laterally inward extending protrusion house an electrode operatively connected to the on-board circuit board and the power source of the housing from which laterally inward extending protrusion extends; wherein the on-board circuit board within each housings of the mandibular piece include instructions that based on data from the one or more sensors activates each motor within housing of the maxillary piece and the electrode simultaneously or sequentially as needed to open an airway of a user. The mandibular piece has a motor housed within each housing thereof and has a cranial-to-caudal driver operatively connected to each motor. The cranial-to-caudal driver is operatively engaged with the maxillary piece for cranial and caudal adjustment of the device from instructions stored in the nontransitory memory of the on-board circuit board within each housing of the mandibular piece based on data received from the one or more sensors.

[0012] In another aspect, the mandibular repositioning devices have a mandibular piece that has a housing proximate one or both of a left molar portion and a right molar portion and the mandibular device has a laterally inward extending protrusion extending from each housing toward the tongue at a position proximate a lingual muscle of the tongue, wherein each housing of the mandibular piece encloses a power source electrically connected to an on-board circuit board which is in electrical communication with one or more sensors and with an electrode, and wherein the on-board circuit board within each housings include instructions that based on data from the one or more sensors activates each electrode as needed to open an airway of a user.

[0013] In yet another aspect, the mandibular repositioning devices have a mandibular piece that has a housing proximate one or both of a left molar portion and a right molar portion and the mandibular device has a laterally inward extending protrusion extending from each housing toward the tongue at a position proximate a lingual muscle of the tongue, wherein each housing of the mandibular piece encloses a power source electrically connected to an on-board circuit board and to a motor, wherein the on-board circuit board is in electrical communication with one or more sensors enclosed within the laterally inward extending protrusion and the motor has a cranial-to-caudal driver operatively connected thereto. The cranial-to-caudal driver is operatively engaged with the maxillary piece for cranial and caudal adjustment of the device from instructions stored in the nontransitory memory of the on-board circuit board based on data received from the one or more sensors.

[0014] In all aspects, the tooth covering of each of the maxillary piece and the mandibular piece connects to or covers one or more teeth of a user or is a full bite mold of a user's teeth.

[0015] In all aspects, each housing of the mandibular piece and of the maxillary piece is removably attachable thereto.

[0016] In yet another aspect, the mandibular repositioning devices have a maxillary piece that has a palate housing portion and/or a buccal housing portion extending from one or both of a left molar portion and a right molar portion, wherein each of the palate housing portion and buccal housing

portion enclose a power source electrically connected to an on-board circuit board which is in electrical communication with one or more sensors and with an electrode, and wherein the on-board circuit board within each housings include instructions stored in nontransitory memory that based on data from the one or more sensors activates each electrode to stimulate a preselected muscle that is in contact with the palate housing portion or buccal housing portion.

[0017] In all aspects, mandibular lingual repositioning devices are disclosed that have a mandibular piece having a first teeth covering and having a housing proximate each of a left molar portion and a right molar portion, a protrusive flange extending cranially from each housing, and a stimulator protrusion extending from each housing toward the tongue at a position to contact a lingual muscle of the tongue. Each housing of the mandibular piece encloses a power source electrically connected to a motor, to an on-board circuit board, and to an electrode within the stimulator protrusion. Further, a first driver is operatively connected to the motor for cranial and caudal adjustments. The device has a maxillary piece having a second teeth covering and having a housing proximate each of a left molar portion and a right molar portion. Each housing of the maxillary piece encloses a power source electrically connected to a motor and to an on-board circuit board and has a second driver operatively connected to the motor for anterior and posterior adjustments. The maxillary piece sits on the mandibular piece with the first driver operatively engaged with the maxillary piece and the second driver operatively engaged with the protrusive flange of the mandibular piece.

[0018] In all aspects, the on-board circuit board includes a receiver and a transmitter and at least one of the stimulator protrusions houses therein one or more sensors selected from the group consisting of a pulse oxygen sensor, a vibration and airflow sensor, a pH sensor, a doppler ultrasound sensor, an M-Mode ultrasound sensor, a 2D ultrasound sensor, 3D ultrasound sensor, a pressure plate sensor for measuring bruxism, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, and a cardiac trans-oral echocardiography sensor. In one embodiment, a first sensor of the one or more sensors is a pulse oximetry sensor and a second sensor of the one or more sensors is a vibration and airflow sensor. The on-board circuit board has a microprocessor having instructions to activate the motors and stimulator simultaneously, independently, or sequentially. The on-board circuit board receives data from the one or more sensors and activates the motors and the stimulator as needed to increase the opening of an airway of the user.

[0019] In all aspects, the first driver can be a flat plate. In one embodiment, the protrusive flange has a bend that orients the free end thereof generally toward the posterior and the second driver has a head shaped to fit the shape of the posterior side of the protrusive flange. The protrusive flange is releasably attachable to the housing of the mandibular piece. In another embodiment, the protrusive flange has a concavely-shaped anterior surface mated to the second driver, and the second driver has

a convexly-shaped head to match the shape of the concavely-shaped anterior surface of the protrusive flange.

[0020] In all aspects, mandibular lingual repositioning systems are disclosed that have a mandibular lingual repositioning device described above that include one or more sensors in at least one stimulator protrusion and a controller station in wireless communication therewith. The controller station has a circuit board comprising a microprocessor, a receiver, and a transmitter, and the microprocessor comprises nontransitory memory having firmware and learning algorithms stored therein. The receiver receives data from the one or more sensors of the mandibular lingual repositioning device, while used by a user, and the microprocessor processes the data and transmits movement instructions to the microprocessors in each of the on-board circuit boards in each housing of the mandibular lingual repositioning device, thereby directing cranial to caudal adjustments, anterior to posterior adjustments, and activation of the stimulator. These movements are directed by the controller station simultaneously, independently, or sequentially. In all aspects, the receiver and transmitter of the controller station communicate with a database of a physician and/or the internet or personal electronic devices. The controller station can include a display screen and have input and output ports for electrical interconnection to a power source and/or other electronic devices and/or houses a rechargeable battery. In all aspects, the controller station can have a first charging space for the mandibular piece and a second charging space for the maxillary piece.

[0021] In all aspects, mandibular repositioning devices have a mandibular piece having a first teeth covering and having a housing proximate each of a left molar portion and a right molar portion, a protrusive flange extending cranially from each housing, and a maxillary piece having a second teeth covering and having a housing proximate each of a left molar portion and a right molar portion. Each housing encloses a power source electrically connected an on-board circuit board and the housings of the maxillary piece further have the power source electrically connected to a motor operatively connected to a drive for anterior and posterior movements of the mandibular piece. The maxillary piece sits on the mandibular piece with the driver operatively engaged with the protrusive flange. The protrusive flange has a concavely-shaped anterior surface mated to a convexly-shaped head of the driver shaped to match the concavely-shaped anterior surface of the protrusive flange. The protrusive flange has a midpoint between opposing ends, and the concavely-shaped anterior surface thereof is an arc of a circle having its center at the temporomandibular joint of the user and a radius terminating at the midpoint or offset above or below the midpoint and defines an angle θ_1 relative to a free end of the opposing ends and defines an angle q_2 relative to an opposing end. The midpoint is approximately at a point where the mandible is open at about 13 degrees. In one embodiment, θ_1 and q_2 are in a range of 12 to 15 degrees. In another embodiment, θ_1 and q_2 are a combination of angle values that sum to 30 degrees, and typically θ_2 is different than q_1, and θ_1 may be greater than q_2.

[0022] In some example embodiments, the protrusive flange is releasably attachable to the housing of the mandibular piece.

[0023] In another aspect, mandibular repositioning devices have a mandibular piece having a first teeth covering and having a housing proximate each of a left molar portion and a right molar portion, wherein each housing encloses a power source electrically connected to an on-board circuit board and to a motor, and a first driver oriented to move caudally and cranially, and a maxillary piece having a second teeth covering. The maxillary piece sits on the mandibular piece with the first driver operatively engaged with the maxillary piece to open or close the mouth of the user. The mandibular piece has a protrusive flange extending cranially from each housing, and the maxillary piece has a housing proximate each of a left molar portion and a right molar portion thereof. Each housing of the maxillary piece encloses a power source electrically connected to a motor and to a circuit board and has a second driver operatively connected to the motor and in operative engagement with the protrusive flange for anterior and posterior movements of the mandibular piece. The protrusive flange can be releasably attachable to the housing of the mandibular piece. In one embodiment, the protrusive flange has a concavely-shaped anterior surface mated to the second driver, and the second driver has a convexly-shaped head to match the shape of the concavely-shaped anterior surface of the protrusive flange. In another embodiment, the protrusive flange has a bend that orients the free end thereof generally toward the posterior and the second driver has a head shaped to fit the shape of the posterior side of the protrusive flange.

[0024] In all aspects, lingual repositioning devices are disclosed that have a mandibular piece having a teeth covering having a left molar portion and/or a right molar portion and a first housing proximate at least one of the left molar portion or the right molar portion. The first housing includes a stimulator protrusion extending therefrom at a position to extend toward a tongue of a user and to contact a lingual muscle of the tongue. The stimulator protrusion encloses a stimulator, and the first housing encloses a power source electrically connected to an on-board circuit board and electrically connected to an electrode of the stimulator. The on-board circuit board includes a receiver, a transmitter, and a microprocessor having instructions to activate the stimulator. The stimulator protrusion can enclose one or more sensors in communication with the microprocessor of the on-board circuit board, which are selected from the group consisting of a pulse oxygen sensor, a vibration and airflow sensor, a pH sensor, a doppler ultrasound sensor, an M-Mode ultrasound sensor, a 2D ultrasound sensor, 3D ultrasound sensor, a pressure plate sensor for measuring bruxism, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, and a cardiac trans-oral echocardiography sensor. In all aspects, the on-board circuit board receives data from the one or more sensors and activates the stimulator in the first housing as needed based on the data to open an airway of a user. In all aspects, a second housing proximate the other of the left molar portion or the right molar portion can be present have a stimulator protrusion extending therefrom at a position to extend toward a tongue of a user and to

contact a lingual muscle of the tongue. The stimulator protrusion encloses a stimulator, and the second housing encloses a power source electrically connected to an on-board circuit board and electrically connected to an electrode of the stimulator. The stimulator protrusion of the second housing can enclose a first sensor and/or a second sensor in communication with the microprocessor of the on-board circuit board, which are selected from the group consisting of a pulse oxygen sensor, a vibration and airflow sensor, a pH sensor, a doppler ultrasound sensor, an M-Mode ultrasound sensor, a 2D ultrasound sensor, 3D ultrasound sensor, a pressure plate sensor for measuring bruxism, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, or a cardiac trans-oral echocardiography sensor. In one embodiment, the first sensor and the second sensor of the second housing are different from one another and are different from the one or more sensors of the first housing.

[0025] In all aspects, the on-board circuit board of the second housing includes a receiver, a transmitter, and a microprocessor having instructions to activate the stimulator in the second housing. The on-board circuit board of the second housing receives data from the first sensor and/or the second sensor and activates the stimulator in the second housing as needed based on the data from the first sensor and/or the second sensor to open an airway of a user.

[0026] In one embodiment, the first housing and/or the second housing, if present, is removable attachable to the teeth covering. The teeth covering can be a bite and mold disposable plastic teeth covering. The first housing may be slidably received on the teeth covering or have a snap fit to the teeth covering.

[0027] In another aspect, mandibular lingual repositioning systems are disclosed that include a mandibular lingual repositioning device described herein that include one or more sensors and a controller station in wireless communication with the mandibular lingual repositioning device. The controller station has a circuit board which includes a microprocessor, a receiver, and a transmitter. The microprocessor has non-transitory memory having firmware and learning algorithms stored therein. The receiver receives data from the one or more sensors, while used by a user, and the microprocessor of the controller station processes the data and transmits stimulator activation instructions to the microprocessor of the on-board circuit board. In all aspects, the receiver and transmitter of the controller station communicate with a database of a physician, the Internet, a personal electronic communication device and combinations thereof. The controller station includes input and output ports for electrical interconnection to a power source and/or other electronic devices, and has a first charging unit for the mandibular piece and a second charging unit for the maxillary piece. Each on-board circuit board includes a receiver, a transmitter, and a microprocessor having instructions to activate the motors simultaneously linearly translate the driver.

[0028] In all aspects, maxillary devices are disclosed that have a first housing connectable to a tooth of a user or connectable or integral with a teeth covering. The first housing encloses an on-board circuit board and a power source and comprises a tooth connecting portion, a palate housing

portion and/or a buccal housing portion extending from the connecting portion. Each of the palate housing portion and the buccal housing portion encloses therein a stimulator having an electrode electrically connected to the on-board circuit board and the power source. The teeth covering can have a left molar portion and a right molar portion, with the tooth connecting portion of the housing connected to or integral with the teeth covering. A second housing proximate the other of the left molar portion or the right molar portion can be present. The second housing encloses an on-board circuit board and a power source and comprises a tooth connecting portion, a palate housing portion and/or a buccal housing portion extending from the connecting portion. Each of the palate housing portion and the buccal housing portion encloses therein a stimulator having an electrode electrically connected to the on-board circuit board and the power source of the second housing.

[0029] In all embodiments, the power source can be a rechargeable battery and the first housing and the second housing, if present, each have a charging member in an exterior surface thereof that is in electrical communication with a rechargeable battery. Each on-board circuit board includes a receiver, a transmitter, and a microprocessor having instructions to activate the stimulator. Each palate portion and each buccal portion can enclose a sensor in electrical communication with the microprocessor of the on-board circuit board. The sensor is selected from the group consisting of a pulse oxygen sensor, a vibration and airflow sensor, a pH sensor, a doppler ultrasound sensor, an M-Mode ultrasound sensor, a 2D ultrasound sensor, 3D ultrasound sensor, a pressure plate sensor for measuring bruxism, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, a cardiac trans-oral echocardiography sensor, and combinations thereof.

[0030] In operation, the on-board circuit board receives data from the sensor(s) and activates the stimulator in either or both of the palate portion and the buccal portion as needed based on the data to stimulate a preselected muscle in contact with the palate portion or the buccal portion.

[0031] The first housing can include a medicament dispenser in electrical communication with the microprocessor of the on-bard circuit board. In operation, the on-board circuit board receives data from the sensor(s) and activates the medicament dispenser to dispense a medicament to a user's oral cavity. The medicament dispenser includes a reservoir housing the medicament and can include a plurality of doses, which can be in pellet, tablet, powder, or liquid form. The medicament dispenser has a dispenser head open or openable for communication with the oral cavity. In all embodiment, the maxillary device can include a controller station having a charging unit for the maxillary device.

[0032] In another aspect, mandibular devices are disclosed that have a first housing connectable to a tooth of a user or connectable or integral with a teeth covering. The first housing encloses an on-board circuit board and a power source and comprises a tooth connecting portion and a sublingual portion extending from the tooth connecting portion. The sublingual portion encloses a sensor and a medicament dispenser each of which are in electrical communication with the microprocessor of the on-board circuit board. In operation, the on-board circuit board receives data from the sensor and

activates the medicament dispenser to dispense a medicament to a user's oral cavity based on data from the sensor. In all aspects, the medicament dispenser includes a reservoir housing a plurality of doses of the medicament such as a pellet, a tablet, a powder, or a liquid. In one embodiment, the medicament is nitroglycerin and the sensor is a pulse oxygen sensor, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, or a cardiac trans-oral echocardiography sensor. The mandibular device includes a controller station having a charging unit for the mandibular device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Many aspects of the disclosure can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale, emphasis instead being placed upon clearly illustrating the principles of the present system.

[0034] FIG. 1 is a left-side view of a first embodiment of a mandibular lingual repositioning device.

[0035] FIG. 2 is a side, perspective view of the mandibular piece of the mandibular lingual repositioning device of FIG. 1.

[0036] FIG. 3 is a side, perspective view of the maxillary piece as it articulates and fits with the mandibular lingual repositioning device of FIG. 1.

[0037] FIG. 4 is a cross-sectional view of the mandibular lingual repositioning device along line 4-4 in FIG. 1.

[0001] FIG. 5 is front, perspective view of a controller station for use with the devices disclosed herein.

[0038] FIG. 6 is an enlarged view of the left movement mechanism of the mandibular lingual repositioning device of FIG. 1.

[0039] FIG. 7 is a an enlarged view of an alternate embodiment of the left movement mechanism of the mandibular lingual repositioning device.

[0040] FIG. 8 is an enlarged side view of an embodiment of a protrusive flange.

[0041] FIG. 9 is a side, perspective view of an embodiment of a mandibular device having at least a stimulator electrode therein.

[0042] FIG. 10 is an enlarged cross-sectional view of the mandibular device along line 9-9 in FIG. 9.

[0043] FIG. 11 is a cross-sectional view of another embodiment of a mandibular device that is removable attachable to a teeth covering.

[0044] FIG. 1211 is a schematic illustration of a system in operative communication with the MRLD of FIG. 1 or the mandibular device of FIG. 8.

[0045] FIG. 13 is a rear, perspective view of a maxillary device having at least a stimulator electrode therein.

[0046] FIG. 14 is a cross-sectional view along line 14-14 of FIG. 13.

[0047] FIG. 15 is an enlarged view of a second embodiment of a connecting portion of the maxillary device.

[0048] FIG. 16 is a longitudinal cross-sectional view of an embodiment of a maxillary device having a medicament dispenser.

[0049] FIG. 17 is a left-side view of the maxillary device of FIG. 2 modified to include a digital camera or digital video recorder.

[0050] FIG. 18 is a side view of an embodiment of a mandibular repositioning device that provides Dynamic Continuous Open Airway Technology (DCOAT) to the user.

[0051] FIG. 19 is a side perspective view of the mandibular piece of the mandibular repositioning device of FIG. 18.

[0052] FIG. 20 is a model comparing the movement of the mandible of a user having the mandibular repositioning device of FIG. 18 against a commercially available mandibular repositioning device.

[0053] FIG. 21 is a mathematical model of how to position and determine the convex and concave curvatures of the protrusive flange and the driver flange of a mandibular reposition device.

[0054] FIG. 22 is a side view of another embodiment of a mandibular repositioning device that provides Dynamic Continuous Open Airway Technology (DCOAT) to the user.

[0055] FIG. 23 is a front view of the device of FIG. 22 in a full-open mouth position.

DETAILED DESCRIPTION

[0056] The following detailed description will illustrate the general principles of the invention, examples of which are additionally illustrated in the accompanying drawings. In the drawings, like reference numbers indicate identical or functionally similar elements.

[0057] Referring now to FIGS. 1 to 4, a mandibular lingual repositioning device (MLRD) that is dynamic in its movement of the jaw(s) and tongue is represented collectively in FIG. 3 by reference number 100. The MLRD 100 has a maxillary piece 102 seated on a mandibular piece 104 for operative communication of drivers built therein.

[0058] Turning to FIGS. 1 and 4, the mandibular piece 104 is shown, which has a first teeth covering 106 and has a housing 108 proximate each of a left molar portion 110 and a right molar portion 112. A protrusive flange 114 extends cranially from each housing 108, and a stimulator 116 extends from each housing 108 toward the tongue at a position to lie under the tongue in contact with lingual muscles, in particular the Genioglossus (GG), the Geniohyoid (GH), sub-mentalis (SM), and Glossopharyngeal (GP). The stimulator protrusion 116 of each housing 108 should be fitted to the user/custom made for the user to ensure proper contact with the lingual muscles. Each stimulator portion 116 while appearing somewhat boxy-looking in the drawings, is more preferably molded of moldable material suitable for use in a human oral cavity and has smooth transitions to its shape and

is shaped to match the shape of the user's mouth, especially to sit under the tongue in contact with the base of the tong and the floor of the mouth as shown in FIG. 4. The moldable material may be any of those commercially available or hereinafter developed for use in a human oral cavity.

[0059] Referring now to the transverse cross-section of FIG. 4, each housing 108 encloses, in a fluid-tight manner, a power source 120 electrically connected to a motor 122, to a circuit board 124, and to the stimulator 116. A first driver 130 is operatively connected to each motor 122 for cranial to caudal adjustments of the device 100. The first driver 130 is linearly translatable by linkages 134 operatively connected to the motor 122 within its housing 108 as shown in FIG. 3. The linkages 134 will be fluid-proof, heat-resistant and acid-resistant and thus able to withstand the conditions found within the oral cavity of a user.

[0060] With reference to FIGS. 2 and 3, the maxillary piece 102 is shown, which has a second teeth covering 107 and has a housing 109 proximate each of a left molar portion 111 and a right molar portion 113. Referring to the partial cross-sectional view of FIG. 3, each housing 109 encloses a power source 121 electrically connected to a motor 123 and to a circuit board 125. A second driver 132 is operatively connected to each motor 123 for anterior to posterior adjustments of the device 100. The second driver 132 is linearly translatable by linkages 135 operatively connected to the motor 123 within its housing 109.

[0061] In all embodiments, the housings 108 and 109 may be fixedly attached to the respective teeth covering, integral therewith, or removable attachable thereto. When removable attachable, the housings 108, 109 may be slid over a molar portion of the teeth covering, have a snap fit thereto, an interference fit thereto, may be a two-piece compartment that snaps together over a predetermined location of the teeth covering, may be three-dimensionally printed to cover or fit over a portion of the teeth covering. In all embodiments, while the teeth coverings 106, 107 are shown as full coverings for all teeth in the mandible and all teeth in the maxilla, the teeth coverings are not limited thereto. Instead, each teeth covering may be a partial cover for one or more teeth, as such, the mandibular piece 104 may be a two-part configuration having a left and a right portion each with a housing 108 and the maxillary piece 102 may be a two-part configuration having a left and a right portion each with a housing 109.

[0062] In all embodiments herein, each housing 108, 109 is described herein as positioned proximate a molar portion of a teeth covering, but is not limited to any particular size, i.e., the number of teeth to which it is associated. Each housing may be associated with one tooth region, a two-tooth region, a three-tooth region, or whatever number of teeth is needed to accommodate the size and position of the housing and its stimulator protrusion.

[0063] Referring to FIGS. 1, 3, and 4, the protrusive flange 114 of the mandibular piece 104 is an elongate flange that is releasably, removably attached to or may be integral with the housing 108. A releasably, removably attachable protrusive flange 114 is shown in FIGS. 6 and 7 to accommodate an interchangeability of protrusive flanges 114 of different shapes and sizes to provide the best fit for

the user's mouth. In the embodiment of FIG. 1, the protrusive flanges 114 are generally an elongate linear flange protruding cranially from each of the housing 108.

[0064] Turning now to FIGS. 6 and 7, the protrusive flange 114′ is releasably attachable to the housing 108 of the mandibular piece 104. The protrusive flange terminates with a post 144 opposite a free end 142 thereof. The post 142 includes a releasably attachable feature 146, such as a snap fit feature, a friction fit feature, or threaded holes as shown in FIG. 7. The housing 108 defines a receptacle 126 shaped to receive the post 144. The receptacle 126 will have a releasably attachable mating feature 128 that mates with the releasably attachable feature 146 of the post 144. In FIG. 7, the releasably attachable mating feature 128 is a set of threaded holes and screws 129.

[0065] As shown in FIGS. 6 and 7, the protrusive flange 114′ can have a bend 140 on the anterior side of the flange, but this is not required. Here, the posterior side 145 of the protrusive flange 114′ is arcuately shaped as best shown in FIG. 8 as a concave surface, which mates with a driver 132 having a convex surface shaped to match the concavity of the posterior side 145. The midpoint 147, relative to being the middle or halfway point between the free end 142 and the opposing end 143, of the arcuately shaped posterior side 145 defines an arc of a circle having its center at the temporomandibular joint (TMJ) in this illustration and the free end 142 has a width that is smaller than a width of the opposing end 143 of the flange. The arc of the circle is one that defines θ_1 as being any angle with the range of 12 degrees to 15 degrees in increments of whole degrees, half degree, or 0.2 degree increments. The angle of the arc θ_1 defines the amount of protrusion of the mandible with each degree of mouth opening. The larger this angle θ_1, the greater the protrusion with mouth opening. The larger the angle of mouth opening, the larger the protrusion of the mandible. The arcuate surface is customizable to provide a curvature that provides the best forward movement of the mandible for the user in relation to the individual user's mouth shape and size. Depending upon the shape and size of the user's mouth and jaws, the radius defining the point of the arc may be offset by moving this point up or down relative to the midpoint 147, which may change the widths of the free end 142 and the opposing end 143.

[0002] The advantage to the arcuately shaped side 145 of the protrusive flange 114′ is that it will help protrude the mandible forward as the Temporo-Mandibular joint (TMJ) relaxes and the mouth falls open during sleep, wake or any other transitional state of the human mind (such as various Parasomnia create) thus allowing gradual smooth arcuate incremental forward mandibular movement to occur as convex surface 145 of protrusive flange 114′ smoothly glides against concave surface 136 of driver 132′. The maximum protrusive distance (MPD) for anterior movement of the mandible is in a range of 6 mm to 10 mm. Typically, the first 13 degrees of rotation of the mandible about the TMJ during natural, un-aided spontaneous mouth opening does not move the mandible anteriorly, i.e., this rotation does not change or open the airway. Drivers 130, 132 will actively coordinate simultaneous desired amount of vertical and protrusive movements of the mandible (controlled by controller 200, described in more detail below) during this first 13 degrees of mouth opening while

the arcuate opposing gliding movements of convex surface 145 of protrusive flange 114′ smoothly against concave surface 136 of driver 132′surfaces will passively create mild forward movement of the mandible. Driver 132 will ensure constant contact between surfaces 145 and 136 while driver 130 will adjust height of oral cavity and thus increase oral cavity volume while simultaneously stiffening the soft palate and uvula. This entire process will work in synergy (keeping the person's sleep undisturbed) to increase cross-sectional area of upper airway and increase the cubic volume of the oral cavity which in turn allows first sensor 150L/R (through the controller 200) in the stimulator protrusion 116 to appropriately incrementally protrude the base of tongue forward into the increased oral cavity volume utilizing electric stimulation of the tongue nerves and muscles (details described elsewhere in this document), further increasing the cross-sectional area of the upper airway (the tongue forms the anterior wall of the upper airway).

[0003] In the natural state, the mandible must rotate beyond this initial 13 degrees, typically through another 7 to 13 degrees to have an effect on the airway size. In an example, where the arcuately shaped side 145 is based on a 15 degree jaw rotation (end to end) curvature, i.e., q_1 and q_2 are 15 degrees each or they may be any combination of two different angles that add up to 30 degrees. The approximate midpoint 147 of the arc 145 is the point at which transition between angle of q_2 and q_1 occurs and is approximately the point at which the mandible (mouth) is expected to have opened or rotated to the first 13 degrees (12 to15 degree range). Total theta at the point of transition 147 = 180 - (q_1 + q_2). Surface 136 of driver 132 should align with the lower part of surface 145 closer to 143 when the mouth is completely closed (Centric Occlusion (CO) with a Centric Relation (CR) between mandibular and maxillary incisor teeth). Angle of q_2 can be different from angle of q_1, i.e. the arc may or may not be one fixed radius from TMJ. Each of the q_1 and q_2 should remain between the ranges of 12-15 degrees each although both q_1 or q_2 or both could be zero degrees each (1-15 degrees each). These angles could exceed 15 degrees each based on individual needs of the user/patient. Total of (q_1 + q_2) will ordinarily be between 24-30 degrees but could be 1-30 degrees or greater. Theta at point of transition 147 is (180 - (q_1+ q_2)) = 150 to 180 degrees unless angles of q_1 and or q_2 exceeded 15 degrees. An angle of 180 would produce incremental forward protrusive movement of the mandible throughout the entire range of mandibular rotation (CR/CO to MMO) during mouth opening.

[0004] q_2 is primarily useful to control neutral mandibular protrusion during the initial 13 degrees of mandibular rotation (although protrusive flange can protrude the mandible when using MRD with motorized protrusive flange option) but can be adjusted to produce protrusive movement (the more q_2 is, the less the radius of mandibular incisor to TMJ, the less protrusion of the mandible during early rotation or mouth opening and the less q_2 is the more protrusion with each degree of mandibular rotation). On the other hand, q_1 is used to create the majority of the forward mandibular protrusion during the remainder of the mandibular rotation or mouth opening all the way to MMO (Maximum mouth opening). Resistance to mouth opening will also occur during this part of mandibular rotation

due to the resistance from stretching the muscles of the TMJ as the mandible incrementally protrudes with every additional degree of mandibular rotation. Increasing q_1 will cause even more protrusion of mandible and thus also cause incremental resistance to mouth opening created by forward jaw movement. Essentially, if the desired outcome is to keep the mouth closed or barely open (CR/CO position), one could use only q_1 and remove q_2 altogether. This would require an arcuate or non-arcuate straight posterior surface 145 with q_1 of 0-15 degrees from the vertical axis starting at base 143 all the way up to 142 as shown in FIG. 6 with a corresponding surface 136 that is straight non-arcuate surface with a corresponding angle 90 + q_1 or a corresponding arcuate surface that leans back as shown in FIG. 6 or combination of arcuate and non-arcuate surfaces such as shown in FIG. 6. Under these circumstances, the larger the angle of q_1, the greater the protrusion of the mandible with the least amount of mandibular rotation or mouth opening (mm of protrusion for each degree of mandibular rotation) and thus also ensure the highest resistance to mandibular rotation and mouth opening to match the needs of the user/patient. In an example, where the arcuately shaped side 145 is customized with q_1 and q_2 of 15 degrees each as well (total theta = 180-30 = 150) for the sake of simplicity of driving home the point, a mandibular rotation or mouth opening of about 20 degrees will protrude the jaw anteriorly about 5 mm and a mandibular rotation of about 24 degrees will protrude the jaw anteriorly about 11 mm. Since the MPD (Maximum Protrusive Distance with range of 6-10 mm) typically has an absolute maximum of 10 mm, 11 mm is nearly impossible for most people and thus the mechanics of the device create the environment where the mouth will not open to MMO (Maximum mouth opening) of 24 degrees.

[0066] The releasably attachable features of the flange 114′ accommodates the interchangeability of protrusive flanges 114 of different shapes and sizes to provide the best fit for the user's mouth.

[0067] Turning now to FIGS. 18-21, some people in need of Continuous Open Airway Technology (COAT) may suffer from dysfunction or abnormalities of the temporo-mandibular joint (TMJ). These individuals may not have evidence of TMJ disease but may have mild restriction of the range of movement of the TMJ and mandibular advancement. As such, milder advancements of the mandible are needed for these individuals when using a mandibular repositioning device (MRD), such as the MRD 800 of FIG. 18. The MRD 800 has Dynamic Continuous Open Airway Technology (DCOAT) because the mandible will follow Arc_2 of FIG. 20 in which as the mandible drops to open the mouth, the mandible will move forward in small increments because of the shape of the protrusive flange 814 and the driver flange 832, thereby opening the airway. Arc_2 demonstrates that when the mandible opens in 5 degree increments relative to the TMJ, the forward point of the mandible changes as shown in Table 1 below.

Table 1: Arc_2 Degrees of Travel corelated to Mandible position

Degrees of Mouth Opening	Distance from the TMJ (centimeters)

0	7 7/8
5	8 1/8
10	8 3/8
15	8 7/16
20	8 9/16
25	8 3/4

In comparison, Arc_1 demonstrates the movement of commercially available COAT MRDs, which open the jaw, but allow the mandible to fall backward toward the throat.

[0068] Turning back to FIGS. 18 and 19, the MRD 800 has a concave-to-convex curvature moving from the base 816 to the most cranial point 818 of the posterior side 815 (or trailing edge) of the protrusive flange 814 of the mandibular piece 804 and a convex curvature 835 of the anterior side 833 (leading edge) of the driver flange 832. While FIG. 18 only shows the left side of the MRD 800, it is understood that the right side can be the same. The protrusive flange 814 extends cranially from the mandibular piece 804 which has a teeth covering 806 for the lower teeth. The driver flange 832 protrudes laterally outward from the side of the maxillary piece 802 a distance sufficient to engage the posterior side 815 of the protrusive flange 814 with the anterior side 833 thereof The driver flange 832 has a base 834 positioned on the maxillary piece 802, i.e., the base of the driver flange does not extend caudally in an overlapping manner with the mandibular piece 804. The maxillary piece 802 has a teeth covering 807 for the upper teeth. The protrusive flange 814 and the driver flange 832 are not shown in this embodiment to have the housings with the motor and mechanism for moving the flanges to provide the movements described herein for the other embodiment, but they are equally usable with such mechanisms and all the systems described herein.

[0069] The protrusive flange 814 may be molded as an integral portion of the mandibular piece 804, but is preferably a removably attachable flange as described above for other embodiments. When the flange is removable, it may include a hole or depression 860 to receive a tool to activate a release of the fastener holding the removable attachable flange in place on the mandibular piece 804. Likewise, the drive flange 832 may be molded as an integral portion of the maxillary piece 802 or it may be removable attachable thereto. The fasteners for holding the flanges to their respective pieces 802, 804 can be any specifically described herein, and commercially available, or any hereinafter developed.

[0070] The concave-to-convex curvature of the posterior side 815 of the protrusive flange 814 has a concave portion 850 most proximate the base of the protrusive flange. Cranially above the concave portion 850 is the convex section 852. The shape and positions of the concave and convex portions 850, 852 is described in more detail with reference to FIG. 21. The mathematical model in FIG. 21, was created using a scale of 1 cm = 10 mm. Here, the dental

horizontal axis (A_H) is represented by segment BC and runs horizontally between the mandibular teeth (crowns of the teeth) along the plane and the maxillary teeth (crowns) above the plane. Thus, the mandibular coverings part of the MRD lies below the horizontal axis while the maxillary coverings part lies above the horizontal axis. A vertical axis (A_V) is drawn perpendicular to the dental horizontal axis at a position passing between the protrusive flange 814 and the driver flange 832 in the at rest position shown in FIG. 21. The rest position is a position of the mandible at which there is no stress on the TMJ. This axis passes between the mating point V_2 of the protrusive flange 814 and the point P_2 of the driver flange 832. Point A represents the TMJ at rest and an axis parallel to the vertical axis (A_V) is drawn through point A, called the TMJ axis (A_{TMJ}). Point B is the point where the horizontal axis and the angle of the mandible intersect. Point C is the point where the TMJH vertical axis and the horizontal axis intersect. Point D is a mid-point of the length of the segment AC. Point E is a point along the TMJ axis that is at 2/3 of the height (H_{DF}) of the driver flange 832. Point F is the mirror of point D along the TMJ axis and Point G is the mirror of point A along the TMJ axis, i.e., a negative value equal to point D and Point A, respectively, below the horizontal dental axis. Point E1 is the mirror of point E on a vertical axis parallel to the TMJ axis but positioned at the front of the incisors (A_I). Average dimensions were used in FIG. 21, and it is therefore understood that these dimensions may vary from individual to individual based on natural variations of body size, jaw size, head size and variations created by abnormalities of the human body as well.

[0071] The primary concept is to use a tangent (**T**) that is parallel to the lean of the Ramus of the mandible (represented by line segment **AB**) in relationship to the horizontal axis (A_H) that passes between the protrusive flange 814 and the driver flange 832 in the at rest position shown in FIG. 21. This creates an angle within the range of 10° to 50° with the vertical axis (A_V) on the maxillary side of the horizontal axis (A_H), which we call θ_1. For the purpose of the following description and simplicity, 10° was selected for θ_1 and $\theta_1 = \theta_2$. However, θ_1 can be any value within the 10° to 50° range. The tangent (**T**) defines the point V_2 of the protrusive flange 814 and the point P_2 of the driver flange 832 on the convex portions thereof, which are aligned in the at rest position. This is referred to as point V_2P_2 and is a point where three tangents meet to create the tangent (**T**). These are designed to meet at the same point although they do not always have to, especially, if a design for any individual requires a variance from this concept. Also, if the Ramus angle is different in each subject from what we have used for this discussion, T may change.

[0072] The five points labeled in FIG. 21 for the protrusive flange 814 are identified in this paragraph. Point V_1 is the lowest point on the trailing edge 815 of the protrusive flange 414 where it lands on the mandibular covering of the MRD. Point V_2 is where the tangent (T)

coincides with point P_2. Point V_3 is the most cranial point of the trailing edge 815 of the protrusive flange 814. Point V_4 is the lowest point of the leading edge 817 of the protrusive flange 814. Point V_5 is the high point where V_3 reflects and meets the leading edge 817.

[0073] The three points labeled in FIG. 21 for the driver flange 832 are identified in this paragraph. Point P_1 is the lowest point of the leading edge 833 of the drive flange 832. P_2 is the point where tangent (T) coincides with point V_2. Point P_3 is the most cranial point of the leading edge 833.

[0074] At T = 10°, the very front of the incisor part of the MRD to point C (the perpendicular dropped from A) appears to be 84 mm long. The midpoint of this segment is 42 mm (referred to herein as the midpoint length) from either end is at point V_2. This is an average distance and may vary on a case-by-case basis (as will all other measurements). About 4.6 mm above point C is a point that is one third of the height of segment AC measured from the horizontal dental plane, designated as point H. Using point H as a center point, a first arc $V_1 - V_2P_2$ defining the curvature of the concave portion 850 of the trailing edge of protrusive flange 814 is drawn and a second arc $P_1 - P_2 - P_3$ (the entire leading edge of protrusive drive 832 is drawn using a radius 1 ($Ø_1$) of 42 mm (equal to the midpoint length). The 42 mm length for the radius could vary on a case-by-case basis.

[0075] The second arc $P_1 - P_2 - P_3$ defines almost the entire leading edge of the driver flange 832. The radius that will be used to draw the leading edge of the driver flange is about 0.2-0.5 mm shorter than the radius used to draw the trailing edge 815 of the protrusive flange 814 to allow a small play for the purpose of proper articulation. The leading edge 833 of the driver flange 832 has a back-cut portion 854 most proximate the point P_1. P_1 is described by a different radius, radius 4 ($Ø_4$) of 52 mm on average. The center point used to draw the arc for the back-cut portion 854 is point D such that segment EC = ED = 11 mm.

[0076] Point E is created by drawing a horizontal line from the point V_2P_2 such that the angle created by $V_2P_2 - C - V_1 = 10°$ thus allowing the point V_2P_2 to be the point where the tangent T = 10° from the vertical axis. Now extending the horizontal line that passes through the points V_2P_2 and E further to the left allows creation of a point E_1, such that segment $V_2P_2 - E_1 = 42$ mm = segment $V_2P_2 - E$. Extending the line H similarly will allow the creation of H_1. With E_1 as center point using the same radius $Ø_2 = 42$ mm another arch is drawn that starts at V_2P_2 and extends upwards to V_3, thus completing the remainder of the trailing edge of the protrusive flange 814. H_1 may similarly be used and any point between E_1 and H_1 may also be used for the same purpose depending on the amount of convexity required at the top of the protrusive flange 814 to create best mandibular advancement for each individual person.

[0077] To build the leading edge 817 of the protrusive flange 814, Point F was used as the center to draw arc $V_4 - V_5$. This was then smoothed out at the top for a smooth transition to the trailing edge 815 and to avoid creating pointed edges. The convex curvature of the leading edge 817 is oriented with its curvature tilted toward the TMJ such that the most cranial point 818 (point V_5) is more proximate point V_2 than point V_4. However, turning now to FIGS. 22 and 23, an alternate embodiment 800′for the MRD is shown in which the leading edge 817 of the protrusive flange 814 can be more linear, yet still oriented tilted with the most cranial point 818 pointed toward the TMJ. Additionally, FIG. 22 has a back-cut portion 864 to the convex portion 852 most proximate the most cranial point 818, back-cut toward the most cranial point 818. FIG. 23 is a front view of the MRD 800′of FIG. 22 in a full-open mouth position with the back-cut portion 864 of the protrusive flange 814 seated against the back-cup portion 854 of the driver flange 832.

[0078] A user in need of an open airway, most often during sleep, but not limited thereto, inserts the maxillary and mandibular device of any of the embodiments disclosed herein into their mouth and goes about with their activity or goes to sleep. With respect to the shape of the flanges in FIGS. 18-21, when the user moves the mandible downward, such as normal relaxation during sleep, the protrusive flange 814 of the mandibular piece 804 moves along the convex curvature of the driver flange 832, which will move the mandible forward, see the increments of movement set forth in Table 1 above, and naturally opens the airway. As such, sleep apnea can be avoided, prevented or controlled.

[0079] Referring back to FIGS. 1 and 4, at least one stimulator 116, but preferably both stimulators 116, include a first sensor 150L/R and/or a second sensor 152L/R, but preferably both sensors. 150L and 152L stands for the left side of the user and 150R and 152 R stands for the right side of the user. The sensors 150L/R and 152L/R may be selected from a variety of sensors to create which every combination is the most likely to be useful in diagnosing or treating the user. The sensors are selected form the group consisting of a pulse oximetry sensor, a vibration sensor, an airflow sensor, a pH sensor, a combination pulse oximetry/vibration and airflow sensor, an EKG sensor, EEG sensor, EMG sensor, EOG sensor, lactic acid sensor, a pulse transit time (PTT) sensor, an ultrasound sensor (echocardiography), an electro-oculogram sensor, a temperature sensor, a body position or jaw position sensor (such as a potentiometer), an electromyogram sensor, a pressure measurement sensor, a hygrometer sensor, a microphone or sound recording sensor, video recording, and hygroscopic/hydration sensor. In one embodiment the first sensor is a combination pulse oximetry/vibration and airflow sensor and the second sensor is a pH sensor. In another embodiment, the first sensor is a pulse oximetry sensor and the second sensor is a vibration and airflow sensor. Any number of combinations of the sensors

listed above is possible and can best be selected by a medical professional based on data relative to the pre-selected end user.

[0080] The stimulator 116 may also be accompanied by a sensor or sensors that can record EEG (electro-encephalogram), EOG (electro-oculogram), electromyogram (EMG) for the tongue muscles and NC (Nerve conduction) data from the nerves of the tongue, pharynx and muscles of mastication (jaw muscles) and phonation (speech). These sensors may transmit these data to the controller 200 (described in more detail below) through variety of industry standard wireless protocols that are currently in use for wireless EMG, NC and EEG recordings in other skin surface applications in neurology and sleep laboratories. Data from such sensors will be useful for detection of various medical diseases as it will be computed in time-synchronized manner by the controller 200 and cloud based servers in system 300 described in more detail below and will help to determine cause-effect of many medical diseases. The sensors will also provide feedback to controller 200 to gauge effectiveness of electric stimulation of the tongue or forward movement of the tongue and mandible and thus allowing the controller to make fine adjustments to all components of the system.

[0081] The length L of each stimulator 116 will be pre-selected to fit the user's mouth and tongue, in particular for adequate contact with the base of the tongue during sleep. Each stimulator 116 has a single or dual electrode 154 connected to the power source 120 and generates an electrical impulse that travels through the electrode to one or more of the lingual muscles of the tongue identified above, which contracts the lingual muscle(s) to create a forward movement of the tongue. The forward movement of the tongue increases the cross-sectional open airway diameter in transvers, vertical and antero-posterior dimensions, thus increasing the aggregate volume of open airway and exponentially reducing air-flow resistance. The power source for the single or dual electrode can be a direct current (DC) power source or may employ any other technology such as electro-magnetic energy, photon energy among other forms of energy. The electrical impulses' power source will be in volts or microvolts and the current, likely in milli-Amps (usually 2-6 mA), will be pre-selected on a per patient basis. The power, current, and capacity will typically be within a range suitable for effective performance of mated hardware and safe for use with cardiac pacemakers, defibrillators, deep brain stimulators, or spinal cord stimulators.

[0082] The forward movement of the mandible (protrusion) is performed by lateral pterygoids, medial pterygoids and masseter muscles. These are stimulated by the mandibular branch of the trigeminal nerve. The neuronal firing rate drops during sleep relaxing these muscles causing the jaw to fall back (retrusion) and thus allowing the tongue to fall back (retro-glossal movement) into the airway as well creating a narrow airway which is the cause of obstructive sleep apnea, oxygen desaturation, elevated blood-pressure, cardiac arrhythmia, disruption in sleep and nocturnal acid reflux. The transverse stimulator 116 can specifically target these muscle groups and their distributing nerve and stimulate and sense electrical activity of these various muscles individually or together inside the oral cavity.

[0083] Also, the stimulators 116 can stimulate selected muscles to improve their strength. This can be a training or a retraining exercise, for example, after a stroke (swallowing difficulty or speech difficulty) or for children with speech pathologies. If sensors are present in the stimulators 116, the sensors can provide data to the controller station 200 and the system 300 of FIG. 11 to determine which muscle and/or muscle group needs attention. Thus, the shape of exterior surface/housing of the stimulators 116 are shaped and sized to direct each and every sensor, stimulator or combination thereof to the appropriate location inside the oral cavity.

[0084] The pulse oximetry sensor 150 is positioned in one or both stimulators 116 at a position enabling direct contact with the base of the tongue from which data will be collected. The position of the pulse oximetry sensor 150 is generally antero-superiorly positioned for measuring pulse-oximetry through the blood-flow of the tongue. The vibration and airflow sensor 152 is positioned in one or both stimulators 116 at a position suitable for airflow measurements, which can indicate when there is a restriction of airflow, and vibration measurements (sub-sonic and sonic) that are an indication of inaudible and audible snores. The vibration and airflow sensor 152 faces posteriorly to measure snores and airflow resistance/pressure from the airway.

[0085] The power source 120, 121 in all embodiments may be a rechargeable battery. In one embodiment, the rechargeable battery is one or more micro-lithium ion batteries in each housing 108, 109. Solar/light charging energy source that can be recharged by ambient lighting (used in the watch maker industry) or solar power may also be considered for a rechargeable source of energy. The rechargeable battery may have a maximum discharge milli-amperage creating a mechanical mandibular protrusion or retrusion ranging between 1-10 mm in linear dimensions for the movement of the drivers 130, 132.

[0086] As seen in FIGS. 1 and 2, each housing 108, 109 of the mandibular and maxillary pieces, respectfully, include a charging member 118, 119, such as a charging plate, in an exterior surface thereof. In the figures, the charging plate is in a lateral side of the housing 108, 109, but is not limited thereto. As best seen in FIG. 3, the first driver 130 may be a flat plate connected to the motor 122 by the linkages 134.

[0087] The motor 122, 123 in all embodiments may be a single or dual piezoelectric motor having a linearly movable linkage(s). Micro motors based on piezo electric materials are commercially available from Piezo Motor, a company headquartered in Sweden and may be modified as needed for use in the disclosed devices. The motor 122, 123 may include a position sensor.

[0088] As best seen in FIGS. 3 and 6, the maxillary piece 102 sits on the mandibular piece 104 with the first driver 130 operatively engaged with the maxillary piece 102 and the second driver 132 operatively engaged with the protrusive flange 114, 114′, or 114′′ of the mandibular piece 104. Each of the drivers 130, 132 can move the jaws in increments of 0.1 mm up to 2 mm with each movement with a maximum of 12 mm in the respective direction. The protrusive flange 114 , 114′, 114′′, is moveable by the second driver 132 in a range from 0.1 mm to 11 mm and the first driver 130 can lift

the maxillary portion in a range from 0.1 mm to 12 mm. Referring again to FIG. 6, the second driver 132 has a head 136 that is shaped to fit the shape of the posterior side 145 of the protrusive flange 114′. The head 136 has a convexly- shaped anterior side to press against the posterior side 145 of the protrusive flange 114′.

[0089] Turning now to FIG. 9, a mandibular device 101 is illustrated that has just the stimulator 116 and a mandibular teeth covering 105. As such, the maxillary piece can comprise a teeth covering 107 as shown in FIG. 2 without the housings 109 or it can be absent, i.e., the user can just have the mandibular device 101 in their mouth during use. Dual housings 108′ are present with one each proximate a left molar portion 110 and a right molar portion 112. A stimulator 116 extends from each housing 108′ toward the tongue at a position to lie under the tongue in contact with lingual muscles, in particular the Genioglossus (GG), the Geniohyoid (GH), sub-mentalis (SM), and Glossopharyngeal (GP). Each housing 108′ includes a charging feature 118 for recharging any battery(ies) housed therein, as described above.

[0090] Referring now to the cross-section of FIG. 10 through one of the stimulators 116, each stimulator 116 houses therein, in a fluid-tight manner, a first sensor 150, a second sensor 152, and a stimulator electrode 154. In FIG. 10, the first sensor 150, the second sensor 152, and the stimulator electrode 154 are each electrically connected to the power source 120 within housing 108′. The electrical connections may be direct connections to the power source 120, which may be accomplished by a plug-n-play electrical connector 156, or, as represented by the dashed lines, may be accomplished by a plug-in style connector 157 to the microprocessor 159 and thereby to the power source.

[0091] In one embodiment, the first sensor 150 is a pulse oxygen sensor continually measuring oxygen data at the base of the tongue and the second sensor 152 is a vibration/air flow sensor measuring snoring, turbulent flow, and vibrations from inside the user's mouth. As noted above with respect to FIG. 4, multiple other sensors and sensor combinations are possible that will provide data to the microprocessor 159. The circuit board 124 within the housing 108′ is in operative connection to the power source to be powered and to control activation of the stimulator electrode 154 in response to data received by the circuit board 124, more particularly, the microprocessor 159, from the first sensor 150 and/or the second sensor 152. As discussed the microprocessor 159 receives the sensor data, processes the sensor data, and determines whether the stimulator electrode 154 needs activated. Each of the stimulators 116 may include a pH electrode too. The pH electrode will measure the acidity at the back of the tongue, which if too high is an indication of chronic high acid reflux.

[0092] Referring now to the FIG. 11, which is a transverse cross-section through one of the stimulator/sensor protrusions 117 and housings 108′of a mandibular device similar to the mandibular device 101 of FIG. 9. In this embodiment, each housing 108′ and stimulator/sensor protrusion 117, rather than being built as part of the teeth covering 160, are removably attachable to the teeth

covering 160. Each housing 108′ defines a groove 162 shaped to receive therein an end 161 of the teeth covering 160, such that one housing 108′ is removably attached to a first end 161 defining a left molar portion and the other housing 108′(not shown) is removably attached to a second end (not shown) of the teeth covering 160 defining a right molar potion thereof. The groove 162 may have opposing flanges 164 positioned at and parallel with a bottom surface 166 of its housing 108′ and extending toward the open void defined by the groove 162. The groove 162 of each housing 108′may be slid over and be received on the teeth covering, may have a snap fit to the teeth covering, may have an interference fit, or may be fabricated in two parts that can snap into each other over a predetermined location of the teeth covering or may be fabricated with three-dimensional printing over a teeth covering. The illustrated embodiment in FIG. 11 has the housing 108′ slidingly received on the first end 161 of the teeth covering 160 with the flanges 164 resting against bottom surfaces of each of the sides of the teeth covering 160. Regardless of the type of attachment, each housing 108′is movable fore and aft to adjust the position of the stimulator/sensor portion under the correct position under the tongue of the user.

[0093] Since the housings 108′ are removably attachable to the teeth covering 160, each housing and or teeth covering may be disposable or reusable. When the housings 108′ are reusable, the housings are constructed of a material suitable for sterilization between uses, such as by autoclave sterilization. Housed within each housing 108′, in a fluid-tight manner, is a first sensor 150, and an optional second sensor 152, and an optional third sensor 153 or a stimulator electrode 154 or even a high-pressure pellet discharge system. Each of the first sensor 150, the second sensor 152, and the third sensor 153 or the stimulator electrode 154 are electrically connected to the power source 120. The electrical connections may be direct connections to the power source 120, which may be accomplished by a plug-n-play electrical connector 156, or may be accomplished by a plug-in style connector to the microprocessor 159 and thereby to the power source 120. The housings 108′each include a charging member 118 in an exterior surface thereof for coordination with one of the charging units 202, 204 of the controller station 200 of FIG. 5.

[0094] In one embodiment, only the first sensor 150 is present. The first sensor 150 may be, but is not limited to, a pulse oxygen sensor, a vibration and airflow sensor, a pH sensor, a doppler ultrasound, an M-Mode ultrasound, a 2D ultrasound, 3D ultrasound, a pressure plate for measuring bruxism, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, or a cardiac trans-oral echocardiography sensor or a camera/videography system, , or any other sensor identified herein. In one embodiment, the first sensor 150 is a pH sensor. In another embodiment, the first sensor 150 is a pulse oxygen sensor continually measuring oxygen data. The mandibular device 101 is used with the controller station 200 in a diagnostic mode.

[0095] Since there are two housings 108′each having a stimulator/sensor protrusion 117, each housing 108′may have a different type of sensor for the first sensor 150 or one may have a first

sensor 150 and the other may have the stimulator 154. As such, the mandibular device 101 can be used in a diagnostic mode or a treatment mode depending upon the selection of sensors and/or stimulator in the housings 108′, thereby providing great versatility in use. Furthermore, since the housings 108′are removable attachable to the teeth covering 160, the housings 108′can be switched for housings having different sensors in a sequence of nights to assess various parameters of the user or during the day or both night and day. The mandibular or maxillary housings or teeth coverings, when used alone (mandibular or maxillary) should allow most speech functions and thus can be used during the course of a normal day. The data interfaces with standard Bluetooth functionality or WIFI functionality and the controller station may be used as a mobile unit with Bluetooth and WIFI functionality and as such may be carried to work or elsewhere since it has its own rechargeable battery operations. Controller station will be interfaced with proprietary or open platform program that can be securely loaded on variety of computer systems and hand-held smart devices.

[0096] In another embodiment, the first sensor 150 in a first of the housings 108′ is a pulse oxygen sensor continually measuring oxygen data at the base of the tongue and the second sensor 152 is a vibration/air flow sensor measuring snoring, turbulent flow, and vibrations from inside the user's mouth; the second of the housings 108′has a pH sensor as the first sensor and includes the stimulator 154. Here, diagnostic and treatment functions are possible that are coordinated by the system 300 or any of its components such as controller or PC or smart device. The sensors 150, 152 provide data to the microprocessor 159. The circuit board 124 within the housing 108′ is in operative connection to the power source to be powered and to control activation of the stimulator electrode 154 in response to data received by the circuit board 124, more particularly, the microprocessor 159, from the first sensor 150 and/or the second sensor 152 and/or from instructions from the controller station 200 and /or the cloud server as shown in FIG. 12 (described in more detail below) to effect a treatment. For example, if the pH sensor senses an increasing acid condition as the user sleeps and the other sensors measure airflow resistance or decreased airflow, then the stimulator will be activated to open the airway and the system will then determine if the pH decreases. Such a causal relationship may help reduce/prevent significant nocturnal acid reflux and thus minimize or eliminate the use of acid reflux medications. Moreover, the combination of sensors can be selected to determine time synchronization of the pH to other physiological occurrences of the user, such as body position, inspiration, expiration, sleep measurements, oxygenation, bruxism, snoring, apnea, etc. Ideally, a link between acid reflux and other physiological occurrences can be determined and then used for treatment.

[0097] Moreover, using the controller station 200 and cloud server of the system 300, it will be possible to receive data regarding the user's input of food and time consumed to act proactively during sleep based on a correlation of digestion time and acid reflux onset. This capability may be extended to input of any and all medications, physiological data such as BP, EKG and blood sugar, and to administering of any and all medications during the day (prompted to the user through

handheldhand held device) or night (automatically performed if pressure pellet for medication is available to the system to discharge sub-lingually in liquid form or inhaled as micro-aerosol powder form.

[0098] The teeth covering 160 in the embodiment of FIG. 11 can be as simple as a plastic boil and bite mandibular device onto which the housings 108′ are removably attachable. In this manner, the teeth covering 160 is disposable and are readily available. Other teeth coverings 160 are commercially available that are generally cheap and disposable such as ora-guard, sonabul, oral-b etc. However, the teeth covering 160 is not required to be disposable. Instead, the teeth covering 160 can be constructed of a material that is sterilizable such that the teeth covering is reusable by a user or users over a preselected time period while sterilizing the housings 108′and utilizing any combination of housings 108′ having a variety of sensors to monitor as many physiological parameters of the user as selected by administering expert.

[0099] Turning now to FIGS. 13 and 14, a maxillary device 400 that is either integral with a teeth covering 407 or removably attachable to the teeth covering 407 is shown. A teeth covering includes a palatal expander or retainer device as well as mouthpiece covering the teeth. Teeth covering 407 may have one maxillary device 400 at the left molar portion and a second maxillary device (the mirror image of the maxillary device 400 in FIG. 13) at the right molar portion. Each maxillary device 400 has a housing 408 that defines a tooth connecting portion 409 one or both of a buccal housing 410 and a palate housing 411 that each define an internal cavities 412, 413, 415, respectively, in which is housed, in a fluid-tight manner, a stimulator electrode 454, 455 and/or one or more sensors 450, 452 and/or other data collecting devices 456.

[00100] The buccal housing 410, when present, is shaped to fit between the user's teeth and cheek and may extend anteriorly and/or posteriorly to collect data and/or stimulate muscles within the oral cavity. The buccal housing 410 can stimulate the lateral pterygoid muscles to move the jaw forward. The jaw may be moved forward during sleep or while awake. While awake, the stimulator 455 can coordinate muscles of mastication or swallowing.

[00101] The palate housing 411 is shaped/contoured to rest against the roof of the user's mouth in contact with the hard palate and the soft palate and clings to the surface of the mucosa in the mouth in order to have good contact for purpose of stimulation of the muscles of swallowing and of the soft palate. The palate housing 411 extends in any possible direction to acquire physiological data from the oral cavity and to stimulate the lateral pterygoid muscles for protrusive movement of the mandible or stimulate muscles of the soft palate and uvula so as to stiffen these structures to reduce snoring or for detection and treatment of speech or swallowing pathologies. The speech or swallowing pathologies may include, for example, post-stroke recovery or reconstructive surgery of the maxilla-facial region recovery or short frenulum syndrome with associated speech defects or micrognathia syndrome in children such as is seen in pediatric obstructive sleep apnea or in Treacher-Collins syndrome.

[00102] Each housing 408 includes a charging feature 418 in an exterior surface thereof for recharging any on-board power source 420, such as battery(ies), housed within the internal cavities 413, 415 or in any portion of the maxillary or mandibular device, even in remote parts of the device, i.e., there is no requirement for the batteries to be adjacent to the location of sensors. The batteries may be any of those discussed above with respect to other embodiments.

[00103] In FIG. 14, the housing 408 includes a photography and/or videography array 460 having photography and videography units 460a, 460b, 460c positioned to face each side and a bottom of a tooth, respectively, as shown in FIG. 14. The photography and/or videography array 460 can include, but is not limited to, unidirectional or multidirectional collection using single or multiple digital cameras to map dental structure, oral cavity structure, airway structure etc. and record sounds. When intended to map the oral cavity or airway structure, the unidirectional or multidirectional units are oriented outward toward the oral cavity rather than toward a tooth. These photography/videography arrays may be used to create recordings of teeth and gums (maxillary or mandibular) for use in general dentistry, endodontic and periodontal applications such as fabrication of enamel, measurement of enamel wear in bruxism, artificial teeth construction, crown construction, gum disease detection and treatment, and for 3-D printing of the mandibular and maxillary devices disclosed herein. When the photography/videography arrays face a tooth, the housing 408 may be configured to slide back and forth over the teeth to create a video or photo recording thereof for dental use. The housing 408 may attached to a wand or a fiberoptic flexible wand that can be manually moved along the teeth by the dentist or physician to help take images of single or multiple teeth or the complete dentition for dental applications or MRD (mandibular repositioning device) construction applications.

[00104] The stimulator electrodes 454, 455 are as discussed above for other embodiments. The sensors 450, 452, 456, 568 include any and all of the sensors discussed above for other embodiments. One of the sensors can be a sound sensor to collect sounds such as those during sleep (e.g., snoring or grinding of the teeth) or those related to speech and swallowing that may be useful to define specific speech defects and swallowing defects. All these functions may be standalone or in synergy with stimulators, mandibular and/or maxillary movement devices, videography, photography, etc.

[00105] In FIG. 14, the first sensor 450, the second sensor 452, and the stimulator electrode 454 are each electrically connected to the power source 420 within the palate housing 411. Likewise, a third sensor 456, a fourth sensor 458, and the stimulator electrode 455 are each electrically connected to the power source 421 within the buccal housing 409. The electrical connections may be direct connections to the power source 420, 421 which may be accomplished by a plug-n-play electrical connector or may be accomplished by a plug-in style connector directly to the microprocessor 459 and thereby to the power source 420, 421.

[00106] In the removably attachable embodiment of FIG. 13, the housing 408 defines a groove 462 shaped to receive therein an end 461 of the teeth covering 407. A first housing 408 is removably

attached to a first end 461 defining a left molar portion and a second housing, if present, is removably attached to a second end (not shown) of the teeth covering 407 defining a right molar potion thereof. The groove 462 may have opposing flanges 464 positioned at and parallel with a bottom surface 466 of its housing 408 and extending toward the open void defined by the groove 462. The groove 462 of the housing 408 may be slid over and be received on the teeth covering, may have a snap fit to the teeth covering, may have an interference fit, or may be fabricated in two parts that can snap into each other over a predetermined location of the teeth covering or may be fabricated with three-dimensional printing over a teeth covering. The illustrated embodiment in FIG. 13 has the housing 408 slidingly received on the first end 461 of the teeth covering 407 with the flanges 464 resting against bottom surfaces of each of the sides of the teeth covering. Regardless of the type of attachment, housing 408 can be movable fore and aft to adjust the position of the stimulator/sensor portion to engage the stimulator 454, 455 with a preselected muscle.

[00107] The housing 408 can be molded from suitable plastics or built with 3-dimensional printing, especially after photographic/video graphic impressions are made of one or all teeth, for example with a system such as Carestream dental imaging. These images can be used to make the housing 408 a single tooth just like putting on a temporary crown. This would be a removable, disposable or reusable option.

[00108] Turning now to FIG. 15, an alternate embodiment of the tooth connecting portion 409 of housing 408 is shown. Here, the tooth connecting portion 409 defines a clasp 500 that is elastically deformable to fit over a single tooth or a plurality of teeth. The clasp 500 defines an arcuate shaped opening 502 that receive a tooth or teeth therein and has opposing teeth side flanges 504 that seat against opposite sides of the tooth/teeth or gums. The clasp 500 is made of an elastic material that will stretch open as it is fitted over a tooth/teeth and will then return to its original position for a tight fit against the tooth/teeth or gums. To enhance the elastic flexibility of the clasp 500, the body defining the arcuate shaped opening 502 can include a plurality of elongate, slightly arcuate bores 506 passing through the body in a juxtaposed arrangement to the arcuate shaped opening.

[00109] Turning now to FIG. 16, a maxillary device 600 is shown that includes a medicament dispenser 670, but it could just as easily be any of the mandibular devices disclosed herein. The maxillary device 600 has a housing 608 connectable to a tooth of a user or connectable or integral with a teeth covering 607. The housing 608 encloses an on-board circuit board 659 and a power source 620 and comprises a tooth connecting portion 609, a palate housing portion 611 extending from the connecting portion, and a charging feature 618 in an exterior surface thereof for recharging the on-board power source 620. The palate housing portion 611 encloses therein a first sensor 650, and optional second sensor 452, and a medicament dispenser 670 each in electrical communication with a microprocessor of the on-bard circuit board 659. The on-board circuit board 659 receives data from sensors 650, 652 and activates the medicament dispenser 670 to dispense a medicament to a user's oral cavity as needed under pre-selected conditions.

[00110] The medicament dispenser 670 includes a reservoir housing 672 the medicament (i.e., a plurality of doses), which can be in pellet, tablet, powder, or liquid form, and a dispenser head 674 open or openable for communication with the oral cavity. The reservoir 672 is either refillable or removable replaceable with a filled reservoir. The reservoir 672 may be manufactured separated and is insertable into the cavity of the housing 611. The reservoir 672 can likely hold 1, or more doses, for example, 2, 3, or 4 doses of a pre-selected medicament. The total dose of all batches of medication would not exceed the total FDA approved dose for a specified period of time ,exemplified by an 8 hour period.

[00111] In one embodiment, the medicament is radiation pellets for treatment of oral cancer or immuno-therapy. In another embodiment, the medicament is trans-mucosal or sublingual drugs, for example, but not limited to, nitroglycerine, intermezzo, albuterol, ADVAIR® medicine. In an embodiment where the medicament is intermezzo, the sensor is an EEF, EOG, or EMG sensor to detect insomnia and thereafter dispense the intermezzo. In another embodiment, the medicament is nitroglycerine and the sensor is an EKG monitor. Additional sensors are beneficial with this embodiment, including a blood pressure sensor, echocardiography and/or carotid doppler blood flow. In a third embodiment, the medicament is a dry powder micro-aerosol inhalation of insulin to treat diabetes and the sensor is a non-invasive continuous glucose sensor. In a fourth embodiment, the medicament is a bronchodilator and the sensor is a microphone to detect breathing difficulties such as wheezing, for example in asthmatics.

[00112] In one embodiment, the medicament is in pellet form and the pellet is filled with a liquid or aerosolized form under pressure therein. The pellet is rupturable, meltable, pierceable. or dissolvable A rupturable pellet ruptures upon application of pressure, such as being squeezed by a driver of a piezo electric motor. A meltable pellet open upon application of heat, such as heat from the power source via a heating electrode. A pierceable pellet is opened by a micro-needle within housing 611. A dissolvable pellet is simply ejected into the oral cavity and dissolves in the saliva. Each pellet is a single dose unit of the selected medicament relative to the user.

[00113] As in the embodiment of FIGS. 1-3, up to four housings, a right and a left maxillary housing and a right and left mandibular housing, can be present and each could include a sensor and a medicament dispenser. As such, up to four or more medicament reservoirs 672 could be present and each can have a plurality of doses of a medicament. Different medications could be installed in different housing, each with an appropriate sensor for the medicament. If only one medication is installed in the user's device, then the medication and the sensor may be in the same housing or in different housings.

[00114] Turning now to FIG. 17, any of the maxillary devices disclosed herein may additionally include a forward facing photography/videography system 700, which includes a digital camera or video recorder 702 facing forward. The maxillary device here is the one from FIG. 2, modified to have an integrally molded recorder housing 704 which houses the digital camera or video recorder

702. The digital camera or video recorder 702 is electrically connected to the on-board circuit board within housing 109 or includes its own wireless transmitting system to send the data to the on-board circuit board within housing 109 or to an off-board microprocessor discussed below.

[00115] Each of the features disclosed with respect to the maxillary devices of FIGS. 13-17 are equally applicable to any of the mandibular and maxillary devices of FIGS. 1-12.

[00116] Turning now to FIGS. 5 and 12, a controller station 200 is illustrated for operatively controlling any of the mandibular lingual repositioning devices 100, 101 described above, which together define a system 300 schematically illustrated in FIG. 12. The controller station 200 has a housing 201 defining a first charging unit 202 for receipt of the maxillary piece 102 and a second charging unit 204 for receipt of the mandibular piece 104. The first and second charging units 202, 204 may be receptacles defined in a surface of the housing 201. In another embodiment, the first and second charging units 202, 204 may be generally flat plates. The housing 201 has a display screen 203 for displaying information to a user and one or more ports 206 for connecting the charging station to power, other devices, and/or the internet. Alternately, instead of ports 206, the housing 201 can enclose wireless communication technology for other devices 310, for example, but not limited thereto, a printer, speakers, tablets, laptops, cellular phones, smart watches, and other cloud-based devices. The controller station 200 may include sensors to record ambient room conditions, such as light, temperature, humidity, noise/sound, etc. The controller station 200 optionally is battery powered and may include a rechargeable battery. The controller station 200 may be portable.

[00117] Alternately, rather than having the first and second charging units 202, 204 integrated into the controlling station 200, a separate charging station (not shown) having a first and second charging unit is possible. The charging station may be portable.

[00118] When the charging station is separate from the controller station 200, the controller station may be incorporated into a hand-held smart device and such a smart device would share blue tooth, WIFI, Video, audio and communication capability with sensors. In one embodiment, the controller can be a proprietary software program for use with or an App (software application) having full functionality to function like the controller station 200. System 300 and controller station 200 in all its embodiments will be HIPPA and HITECH compliant for purpose of medical privacy. Interface with the wide variety of electronic health formats (EHR) would allow system 300 and controller station 200 and its operated systems to be available for real-time data download and upload, active health care worker involvement in user's health care needs and would permit the health care worker to operate and alter any treatment and access and interpret diagnostic information provided by the system. As such controller station 200 and system 300 would allow newer formats of health care provisions such as tele-medicine and others yet to be defined. System 300 may be integrated into a full-function health care software-hardware system for patient assessments (such as telemedicine), tests, treatments and medications.

[00119] The controller station 200 encloses a circuit board having a microprocessor, including memory (non-transitory computer readable media) in which is stored firmware and learning algorithms, having a receiver of electronic communications, and having a transmitter of electronic communications, including wireless communication capabilities to electronically communicate with at least the MLRD 100, 101 for real-time communications with the sensors on board the MLRD. The MLRD 100, 101 has microprocessors on-board with a transmitter to transmit raw data from all sensors, stimulators and pressure pellets exemplified by the pulse oximetry sensor, the vibration and airflow sensor, lingual stimulator, lateral pterygoid stimulator, medial pterygoid or masseter stimulator, EKG sensor, sub-lingual nitroglycerine pellet discharge, etc. to the controller station 200 in real-time aided by system 300 for processing into executional commands exemplified by movements of the first driver and/or the second driver and activation of the stimulator for tandem or synchronized movements and activation thereof, i.e., simultaneous, independent, or sequential activation of the motors and the stimulator, training of muscles of speech or swallowing including the sequence of movement and strength and duration of current or release of a medication for sublingual or aerosolized use. The controller station 200 can simultaneously transmits the instructions to the MLRD 100, 101 microprocessors in each housing 108, 109, 108′ which implement the instructions, exemplified by synchronizing the cranial to caudal adjustments, the anterior to posterior adjustments, and activation of the stimulator etc. The MLRD may also operate as a stand-alone mandibular protrusive and vertical advancement device or as a stand-alone lingual/pterygoid stimulator device or a timed-medication release device as preferred by treating health care provider.

[00120] The circuit board of the controller station 200 receives data from the pulse oximetry sensor and/or the vibration and air sensor and activates the motors and the stimulator as needed after a pre-selected number of breaths of the user. The firmware and algorithms, including learning algorithms as well as standard algorithms, stored in the memory of the circuit board may define the pre-selected number of breaths to be every breath, every other breath, every five breaths, or an absence of breath(s). Since the movements of the MLRD 100, 101 are done in real-time, the airway of the user can be opened without disturbing the sleep of the user.

[00121] The controller station 200 has a microprocessor configured to process the data and instruct the MLRD 100, 101. However, the controller station 200 can communication with a server, such as a cloud server, for further processing if desired, or for additional memory storage and/or communication of the data to authorized healthcare providers and/or sleep analysis experts, etc. and/or communicate with a database of said person. This intercommunication of databases can create therapeutic interventions and diagnostic testing of a user while at home or across continents. This system 300 enables an authorized healthcare provider to monitor and record patient data in real time, learn the patient, and alter the patient's treatment in real-time. The communications to and from the server can be through a wired or a wireless connection. The system 300 can also be configured to send data to a pharmacy.

[00122] The server can also send commands, configuration data, software updates, and the like to the controller station 200 in whatever form it may exist. The configuration data may include, but is not limited to, configuration parameters for the system 300, configuration parameters for a particular user, and/or notifications, feedback, instructions, or alerts for the user.

[00123] The system 300, in addition to the MLRD 100, 101 can wirelessly communicate with additional sensors connected to the user to provide a broader data set for a more complete picture of the user's physiology. For example, electrocardiogram (EKG), electromyography (EMG), electrooculography (EOG), electroencephalography (EEG) sensors, echocardiography, blood pressure monitoring systems, and sensors sensing environmental conditions, such as temperature, ambient light, and humidity. The system may include a camera for video recording through the controller station 200 to evidence any nocturnal seizures, sleep-walking, other movement or violent disorders during sleep.

[00124] In operation, data from the sensors on the MLRD 100, 101, such as oxygen measurements and pulse data, is sent to the controller station 200 to be processed by the microprocessor to determine how much movement of the protrusive flange by activation of the second driver is needed, how much movement of the first driver is needed to separate the jaws of the user, and if and when to stimulate the transverse lingual muscle of the tongue to move the tongue forward. After some breaths, the controller station 200 may determine to stimulate the tongue and activate the second driver to move the mandibular piece, and hence the jaw of the user, forward (anterior) or backward (posterior) direction. In other instances, the controller station 200 may determine to stimulate the tongue and activate both the first driver and the second driver to separate the jaws and move the mandibular piece forward in order to adequately open the airway of the user.

[00125] The system 300 also creates three-dimensional images and videos of breathing, cardiac function, carotid blood flow data, eye-movements, jaw movements and brain EEG recordings for identification of medical conditions and interventions that may be useful to correct or treat those medical conditions.

[00126] A unique advantage of this system over any other existing systems is that the jaw and tongue can move synchronously, independently, or sequentially during sleep in real-time and in anticipation of impending airway closure and in a provision of a measured response to restriction of airflow as determined by the controller station 200 even before the airway has completely closed; thus, restoring unrestricted airflow even before the patient has completely stopped breathing. This system can see airway obstruction before it happens and will keep the airway constantly open in any body position or depth of sleep. This is a distinct advantage over CPAP/BIPAP or any other mechanical or electrical system that is commercially available in the market. In addition, there are distinct advantages just by the breadth of functionality that has been described above. Any discussions herein directed to the mandibular component, with respect to the controller station 200 and the system 300, are equally applicable to the maxillary component.

[00127] The controller station 200 includes learning algorithms in the memory of the microprocessor that learns a user's sleep patterns and other physiological events and functions during sleep and wake, pathological events and activities during wake and sleep from the data collected over time and creates a "best response" for the simultaneous, independent, or sequential responses exemplified by tensing of the soft palate or Uvula, release of medication or stimulation of the stimulator and activation of the first and second drivers to open the airway or to train muscles of speech, and to synchronize these best responses such as exemplified by certain jaw movements that are associated with particular phases of respiration. The activation of the first and second drivers 130, 132 not only includes advancements, but also retractions of the first and second drivers 130, 132 to relax the jaws in between necessary advancements to open the airway to avoid potential TMJ problems. Any discussions herein directed to the mandibular component, with respect to the controller station 200 and the system 300, are equally applicable to the maxillary component.

[00128] The controller station 200, in the memory of the microprocessor, may include a pre-programmed range for the movements of the first and second drivers 130, 132 based on sleep study data for the user conducted by an authorized healthcare provider. The pre-programmed range can be used by the controller station 200 in a stand-alone or auto servo mode. The pre-programmed range may be determined by simple or multiple linear regression models that employ data from inputs and from previous experiences, which the controller station 200 will be able to forecast ranges for the amount and direction of movements of the drivers 132, 134 and the amount or timing of energy discharge through the transverse stimulator(s). The controller station 200, in the memory of the microprocessor, may include data from tests previously performed on the user and/or the output of algorithms to set the MLRD 100, 101 each day for use just prior to sleep.

[00129] The controller station 200 can operate based on a standalone function or a servo function. In the standalone function, the controller station 200 operates the MLDR 100, 101 based on set parameters such as are exemplified by the movement of the drivers, such as repetitive equal advancement and retraction of the mandible that are not based on active feedback. For example, a set 2 mm movement anteriorly of the mandible during each breath and a 2 mm posterior movement of the mandible after each breath, with a fixed amount of energy discharge to the electrode of the stimulator. The set parameters for the standalone function may be based on data collected from the specific user or may be based on a peer group of like sleep attributes.

[00130] In the servo function, the controller station 200 interactively controls the MLRD 100, 101 during sleep or wake, at home or elsewhere, based on the data collected from the sensors on-board the MLRD in a feedback loop and based on data available from the server. During operation, the continual feedback loop allows incrementally accurate interventions followed by listening to observational inputs exemplified by airflow measurements, video recordings, pulse-oximetry, doppler flow in carotids or advancement of mandible and followed by more interventions exemplified by protrusive or vertical adjustments based on real-time data even after a previous

advancement or incremental increase in energy to stimulate the tongue. The changes to the advancement or application of energy to the stimulator will be capable of producing positive and negative changes regarding movement of the mandible and tongue. For example, the energy applied to the stimulator may be reduced relative to the prior application of energy discharge if the previous discharge of energy caused teeth grinding or cough. In another example, the protrusive movement of the jaw may be reversed if the previous protrusion advancement caused a deleterious change in any of the monitored physiological parameters. In another example training of muscles of swallowing would be altered upon observing retrograde movement of food or appearance of cough or gag.

[00131] Also, in the servo function, data from all sources, server, MLRD, and any other sensors attached to the user that are communicating with the controller station 200, are continuously processed through algorithms that are stored in the memory of the controller or stored in the server. Examples of other sensors includes, but is not limited to, wireless pulse-transit time sensors, and wireless EKG sensor. These two additional sensors would be utilized in addition to the MLRD to diagnose and treat sleep-induced hypertension and/or cardiac arrhythmia such as lack of oxygen to the heart, especially by collecting time synchronized data from the EKG sensor and the pulse oximeter sensor. For example, the server may include data related to sleep attributes and alcohol consumption to make adjustments for the user during sleep after drinking alcohol. For example, it may require a change in current applied to the stimulators 116 after alcohol consumption to effectively stimulate the lingual muscles. The same may be true of a user taking certain medications, especially those that depress brain function. As another example, the server may include data on myriad patients correlating sleep attributes to weight loss. As such, if the user loses 5 or 10 pounds, data from the server can be considered in the algorithm determining how much movement of the jaws is needed and/or whether to stimulate the tongue.

[00132] The system 300 may be used to treat many medical diseases, including but not limited to any type of sleep apnea, bruxism, sleep related GERD, sleep-induced hypertension, snoring, etc.

[00133] The system 300 may be used to diagnose any possible medical conditions related to sleep or while awake, including sleep apnea or other sleep disorders including sleep-induced hypertension, sleep-related cardiac arrhythmia, sleep related seizures, RLS and periodic limb movement disorders and other medical diseases, even those unrelated to sleep. Here, the MLRD 100 or 101 is placed in the user's mouth during a sleep period, such as at night, with the controller station 200 in a "test mode" in which the on-board sensors measure and monitor the user's physiological parameters mentioned above. The test mode is used for multiple sleep periods of over two to 30 days, based on a time period set by a medical professional. For example, the user may have the controller station in "test mode" for seven days. Then, the seven days of data is reviewed by the medical professional to determine whether the user has sleep apnea or any other sleep disorder, and if so, determines the parameters for the standalone mode, which are then stored in the controller station 200. The same system may be used even during the day and outside of the home of the user such as at place of work.

[00134] The system 300 may have a therapeutic mode, which implements the servo function. Here, the feedback loop is on for data from the on-board sensors, which is processed through an algorithm to determine the least amount of anterior and caudal movement to maintain an open airway and the least amount of energy discharge to stimulate the tongue and maintain an open airway and the order in which to take such actions, i.e., simultaneously, sequentially, or individually.

[00135] The device and system disclosed herein have numerous advantages, including artificial intelligence utilizing data collected by the MLRD during use to actively in real-time adjust the MLRD in response to the phases of respiration, degree of obstruction of the airway, snore sounds and vibrations and amount of hypoxemia present relative to each breath irrespective of the stage of sleep of the user. The system is capable of measuring a large number of cardiac, neurological and endocrine sensory inputs as described above exemplified by continuous non-invasive glucose, oxygen, blood pressure, pH monitoring, heart rhythm and temperature etc. The system is capable of photography for creating dental impressions, dentures or to diagnose gum disease etc. The system is capable of executing a large spectrum of functions such as mandible protrusion, administering sub-lingual insomnia medication like Intermezzio or cardiac medication like nitroglycerine or training muscle groups for swallowing or speech. The system is capable of communicating with user, provider, EHR (Electronic Health Record) and pharmacy etc. This system is capable of determining restriction to airflow, increase in velocity of air and turbulence, decreasing levels of oxygen and increasing levels of heart rate, pH monitoring and any other physiological parameter that could be installed in the future with constant inputs of physiological parameters (unlike with CPAP machine or oral appliances that are available in the industry), such as those mentioned above. This collection and processing of data allows the system to actually make adjustments exemplified by the movement of the mandible and tongue prior to closure of the airway and hence will work as a preventative form of treatment for sleep apnea.

[00136] Age and gender specific physiology of the airway and the mouth during sleep are known to affect sleep and cause sleep disorders. The system 300 and 310 will collect data that will enable the development of algorithms that are age and gender specific, which can improve treatment outcomes for future users. System 300 and 310 has ability to create database of all physiological and pathological events measured in real-time and time synchronized with each other in its users and develop algorithms for normal and abnormal manifestations of disease states during wake and sleep and develop new cause-and-effect understanding of these events that have never been observed before. Recording and correlation of these phenomenon with sensors, especially during sleep would help understand conditions such as 'wake-up strokes' (occur during sleep) that account for 14% of all strokes and diagnose conditions like obstructive sleep apnea that occurs with almost 83% of cardiovascular disease, 58% of heart failure and 53% of atrial fibrillation, to name a few.

[00137] The system not only advances movement of the mandible (cranially and anteriorly), but enables a relaxed movement of the mandible (caudally and posteriorly), which allows the

temporomandibular joint to relax periodically to prevent jaw discomfort, temporomandibular joint strain and destabilization, morning stiffness of said joint, and alteration of the user's bite.

[00138] The system 300 can also be used for users that snore, but who do not yet have sleep apnea. The inclusion of the vibration and airflow sensor enables the measurement of the intensity of snoring and can open the airway before the sub-sonic snore has become audible. The inclusion of stimulators of soft palate and uvula can reduce or eliminate snoring in users that do not have sleep apnea yet. Also, the system 300 can be used along with a CPAP machine and enable the CPAP machine to be used at a lower air pressure than a typical setting for user's that cannot tolerate CPAP machine at their typical air pressure.

[00139] In one example, the devices disclosed herein are worn by a user at nighttime and includes sensors to monitor nocturnal silent angina or myocardial ischemia (measured by continuous EKG monitoring) that could cause sudden death or acute myocardial infarction during sleep or wake (especially silent ischemia). With the medical dispenser present, an incident could be treated with release of sublingual nitroglycerine from medicament reservoir while data such as continuous blood pressure recording, EKG, echocardiography and carotid doppler blood flow is continuously recorded and transmitted to the controller station 200 or cloud server 300. The cloud server 300 can then send the data to a monitoring on-call physician, a handheld device or computer to alert the patient, as well to the nearest ER/ED (emergency room) for early ambulance dispatch.

[00140] In other examples, the sensors selected for use in the maxillary and mandibular devices disclosed herein can be those that can diagnose cardiovascular, gastrointestinal, and/or neurological medical conditions. The devices can have sensors and treatment methods to treat the same medical conditions.

[00141] In an athletic environment, the sensors selected for use in the maxillary and mandibular devices disclosed herein can be the pulse-oximetry, heart rate and EKG, PTT with non-invasive blood pressure recording, carotid blood flow, airway resistance and total tidal volume (airflow measurement per breath), EEG recording, respiratory rate measurement, and combinations thereof. Data from these sensors will allow determination of performance restrictions and methods to physiologically improve performance such as legal nutritional supplementation or medications for underlying medical conditions or increasing the size of airway to help improve oxygenation and reduce heart rate during exercise or athletic performance. Further, evaluation of concussion injuries is possible with maxillary and mandibular devices that have EEG sensors, carotid doppler blood flow ultrasound sensor, airway and airflow sensors. The protrusive aspect of the devices can improve airflow after a concussion by increasing the size of airway with electrical stimulation of the tongue when the athlete is unconscious, thereby reducing brain injury from loss of oxygen.

[00142] System 300 can be used for scheduled timed administration of medication through the mechanisms and devices discussed above, especially for those medications best administered while the user is asleep.

[00143] When medicaments are being administered by the devices disclosed herein, the controller station 200 or system 300 would identify a physiological problem of the user from data received from the sensors and/or from data received from an external EKG monitoring system or external blood-glucose monitoring system of the user followed by generation of an executable instruction sent to the device's on-board microprocessor through wireless data system (blue tooth or other protocols) with back-up confirmation system for dangerous medications. The back-up may be the user themselves (smart phone or display screen of controller Station 200) or an on-call nurse or ER physician or authorized health care provider or tele-medicine through a smart handheld device or through videography/audio from a camera or video recorder in the mandibular or maxillary housing. Data related to administration of the medication would require a response the following day prompting replacement of discharged pellets or other forms of the medicament, a visit to the health care provider's office, or a tele-medicine visit.

[00144] It should be noted that the embodiments are not limited in their application or use to the details of construction and arrangement of parts and steps illustrated in the drawings and description. Features of the illustrative embodiments, constructions, and variants may be implemented or incorporated in other embodiments, constructions, variants, and modifications, and may be practiced or carried out in various ways. Furthermore, unless otherwise indicated, the terms and expressions employed herein have been chosen for the purpose of describing the illustrative embodiments of the present invention for the convenience of the reader and are not for the purpose of limiting the invention. Having described the invention in detail and by reference to preferred embodiments thereof, it will be apparent that modifications and variations are possible without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

1. A mandibular repositioning device comprising:

a maxillary piece comprising a tooth covering having a driver flange protruding laterally outward on a right side proximate a backmost teeth mold and/or on a left side proximate a backmost teeth mold, each driver flange having an anterior side with a convex curvature;

a mandibular piece comprising a tooth covering having a protrusive flange extending cranially therefrom positioned to have a posterior side engaged with the anterior side of each driver flange, the posterior side of each protrusive flange has a concave-to-convex curvature from its base toward its most cranial point and a convex portion of the concave-to convex curvature engages the convex curvature of the driver flange in a rest position;

wherein downward movement of the mandibular piece moves the convex portion of the posterior side of the protrusive flange along the convex curvature of the driver flange, thereby moving a user's mandible forward.

2. The device as claimed in claim 1, wherein the protrusive flange is removably replaceably attached to the mandibular piece.

3. The device as claimed in claim 1, wherein the driver flange is removably replaceably attached to the maxillary piece.

4. The device as claimed in claim 1, wherein the convex portion of the curvature of the protrusive flange engages with the convex curvature of the driver flange at a point that is two thirds of the height of the driver flange.

5. The device as claimed in claim 4, wherein the driver flange has a base that is positioned on the maxillary piece.

6. The device as claimed in claim 1, wherein the protrusive flange and the driver flange are positioned to place an engagement point of the convex portion of the concave-to convex curvature with the convex curvature of the driver flange at a midpoint length that is at half the lineal distance from a vertical axis at the front of the incisors (incisor vertical axis) to a point on a parallel vertical axis aligned with the temporo-mandibular joint (TMJ) at rest (TMJ vertical axis).

7. The device as claimed in claim 6, wherein the majority of the convex curvature of the driver flange is defined by an arc having a center at a point on the TMJ vertical axis that is one third of the

height of the driver flange measured from the horizontal dental axis and has a radius length equal to the midpoint length.

8. The device as claimed in claim 7, wherein the convex curvature of the driver flange has a back-cut most proximate a base of the driver flange.

9. The device of claim 8, wherein the back-cut portion is determined by an arc from a center point positioned on the TMJ vertical axis at two thirds of the height of the driver flange measured from the horizontal dental axis.

10. The device of claim 6, wherein a convex curvature of the convex portion of the protrusive flange is defined by an arc having a center at a point on the incisor vertical axis that is at two thirds the height of driver flange measured from the horizontal dental axis and has a radius length equal to the midpoint length.

11. The device of claim 10, wherein a concave curvature of the concave portion of the protrusive flange is defined by an arc drawn from a point on the TMJ vertical axis that is one third of the height of the driver flange measured from the horizontal dental axis and has a radius length equal to the midpoint length.

12. The device of claim 11, wherein the anterior side of the protrusive flange has a convex curvature.

13. The device of claim 1, wherein the maxillary piece has a housing proximate one or both of a left molar portion and a right molar portion, wherein each housing encloses a power source electrically connected to a motor and to an on-board circuit board and has a driver operatively connected to the motor and to the driver flange for anterior and posterior movements of the driver flange; and the mandibular piece has a housing proximate one or both of a left molar portion and a right molar portion and the mandibular device has a laterally inward extending protrusion extending from each housing toward the tongue at a position proximate a lingual muscle of the tongue, wherein each housing of the mandibular piece encloses a power source electrically connected to an on-board circuit board which is in electrical communication with one or more sensors enclosed within the laterally inward extending protrusion, or the maxillary piece has a palate housing portion and/or a buccal housing portion extending from each housing thereof and each palate housing portion and buccal housing portion encloses therein a power source electrically connected to an on-board circuit board which is in electrical communication with one or more sensors.

14. The device of claim 13, wherein the one or more sensors are selected from the group consisting of a pulse oxygen sensor, a vibration and airflow sensor, a pH sensor, a doppler ultrasound sensor, an M-Mode ultrasound sensor, a 2D ultrasound sensor, 3D ultrasound sensor, a pressure plate sensor for measuring bruxism, electroencephalogram (EEG), Electromyography (EMG), electrooculography (EOG), lactic acid sensor, hygroscopic/hydration sensor, video and audio recording, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, and a cardiac trans-oral echocardiography sensor.

15. The device of claim 13, wherein, when the mandibular piece houses the one or more sensors, each on-board circuit within housings of the maxillary piece include a receiver and a microprocessor having an instruction stored in nontransitory memory to activate each motor and each on-board circuit board within housings of the mandibular piece include a receiver, a transmitter, and a microprocessor having an instruction in nontransitory memory to activate each motor within housing of the maxillary piece simultaneously based on data received from the one or more sensors, and, when the maxillary piece houses the one or more sensors, each on-board circuit within the housings of the maxillary piece include a microprocessor having an instruction in nontransitory memory to activate each motor simultaneously based on data received from the one or more sensors.

16. The device of claim 15, wherein the mandibular piece has a motor housed within each housing thereof and has a cranial-to-caudal driver operatively connected to each motor; wherein the cranial-to-caudal driver is operatively engaged with the maxillary piece for cranial and caudal adjustment of the device from instructions stored in the nontransitory memory of the on-board circuit board within each housing of the mandibular piece based on data received from the one or more sensors.

17. The device of claim 15, wherein one or both of the laterally inward extending protrusion house an electrode operatively connected to the on-board circuit board and the power source of the housing from which laterally inward extending protrusion extends; wherein the on-board circuit board within each housings of the mandibular piece include instructions that based on data from the one or more sensors activates each motor within housing of the maxillary piece and the electrode simultaneously or sequentially as needed to open an airway of a user.

18. The device of claim 17, wherein the mandibular piece has a motor housed within each housing thereof and has a cranial-to-caudal driver operatively connected to each motor; wherein the cranial-to-caudal driver is operatively engaged with the maxillary piece for cranial and caudal adjustment of the device from instructions stored in the nontransitory memory of the on-board circuit board within each housing of the mandibular piece based on data received from the one or more sensors.

19. The device of claim 1, wherein the mandibular piece has a housing proximate one or both of a left molar portion and a right molar portion and the mandibular device has a laterally inward extending protrusion extending from each housing toward the tongue at a position proximate a lingual muscle of the tongue, wherein each housing of the mandibular piece encloses a power source electrically connected to an on-board circuit board which is in electrical communication with one or more sensors and with an electrode, and wherein the on-board circuit board within each housings include instructions that based on data from the one or more sensors activates each electrode as needed to open an airway of a user.

20. The device of claim 1, wherein the mandibular piece has a housing proximate one or both of a left molar portion and a right molar portion and the mandibular device has a laterally inward extending protrusion extending from each housing toward the tongue at a position proximate a lingual muscle of the tongue, wherein each housing of the mandibular piece encloses a power source electrically connected to an on-board circuit board and to a motor, wherein the on-board circuit board is in electrical communication with one or more sensors enclosed within the laterally inward extending protrusion and the motor has a cranial-to-caudal driver operatively connected thereto; wherein the cranial-to-caudal driver is operatively engaged with the maxillary piece for cranial and caudal adjustment of the device from instructions stored in the nontransitory memory of the on-board circuit board based on data received from the one or more sensors.

21. The device of claim 1 wherein the tooth covering of each of the maxillary piece and the mandibular piece connects to or covers one or more teeth of a user or is a full bite mold of a user's teeth.

22. The device of claim 1, wherein each housing of the mandibular piece and of the maxillary piece is removably attachable thereto.

23. The device of claim 1, wherein the maxillary piece has a palate housing portion and/or a buccal housing portion extending from one or both of a left molar portion and a right molar portion, wherein each of the palate housing portion and buccal housing portion enclose a power source electrically connected to an on-board circuit board which is in electrical communication with one or more sensors and with an electrode, and wherein the on-board circuit board within each housings include instructions stored in nontransitory memory that based on data from the one or more sensors activates each electrode to stimulate a preselected muscle that is in contact with the palate housing portion or buccal housing portion.

24. A mandibular lingual repositioning device comprising:

a mandibular piece having a first teeth covering and having a housing proximate one or both of a left molar portion and a right molar portion, a protrusive flange extending cranially from each housing, and a stimulator protrusion extending from each housing toward the tongue at a position to contact a lingual muscle of the tongue, wherein each housing encloses a power source electrically connected to a motor, to an on-board circuit board, and to an electrode and one or more sensors within the stimulator protrusion; and wherein a first driver is operatively connected to the motor for cranial and caudal adjustments of the device; and

a maxillary piece having a second teeth covering and having a housing proximate one or both of a left molar portion and a right molar portion, wherein each housing encloses a power source electrically connected to a motor and to an on-board circuit board and has a second driver operatively connected to the motor for anterior and posterior adjustments of the device;

wherein the maxillary piece sits on the mandibular piece with the first driver operatively engaged with the maxillary piece and the second driver operatively engaged with the protrusive flange of the mandibular piece;

wherein the on-board circuit board of each housing of the mandibular piece includes a receiver and a transmitter, and a microprocessor having instructions to activate the motors and stimulator simultaneously, independently, or sequentially, and the on-board circuit board receives data from the one or more sensors and activates the motors and the stimulator as needed to increase the opening of an airway of the user.

25. A mandibular repositioning device comprising:

a mandibular piece having a first teeth covering, a protrusive flange extending cranially from each housing; and

a maxillary piece having a second teeth covering and having a housing proximate one or both of a left molar portion and a right molar portion, wherein each housing encloses a power source electrically connected to a motor and to an on-board circuit board and has a driver operatively connected to the motor for anterior and posterior movements of the driver;

wherein the maxillary piece sits on the mandibular piece with the driver operatively engaged with the protrusive flange of the mandibular piece;

wherein either the mandibular piece or the maxillary piece includes one or more sensors oriented to be positioned in a user's oral cavity to measure parameters indicative of a need to open the user's airway, wherein the one or more sensors are in operative communication with the on-board circuit board;

wherein the on-board circuit board includes a receiver, a transmitter, and a microprocessor having instructions to activate the motors simultaneously to linearly translate the driver.

26. A mandibular repositioning device comprising:

a mandibular piece having a first teeth covering and having a housing proximate one or both of a left molar portion and a right molar portion, wherein each housing encloses a power source electrically connected to an on-board circuit board and to a motor, and a first driver oriented to move caudally and cranially; and

a maxillary piece having a second teeth covering;

wherein the maxillary piece sits on the mandibular piece with the first driver operatively engaged with the maxillary piece to open or close the mouth of the user;

wherein either the mandibular piece or the maxillary piece includes one or more sensors oriented to be positioned in a user's oral cavity to measure parameters indicative of a need to open the user's airway, wherein the one or more sensors are in operative communication with the on-board circuit board;

wherein the on-board circuit board includes a receiver, a transmitter, and a microprocessor having instructions to activate the motors simultaneously to translate the first driver.

27. The device as claimed in claim 26, wherein the mandibular piece has a protrusive flange extending cranially from each housing, and the maxillary piece has a housing proximate one or both of a left molar portion and a right molar portion thereof, wherein each housing of the maxillary piece encloses a power source electrically connected to a motor and to a circuit board and has a second driver operatively connected to the motor and in operative engagement with the protrusive flange for anterior and posterior movements of the mandibular piece.

28. The device as claimed in any of claims 24 to 27, wherein the protrusive flange has a concavely-shaped anterior surface mated to the second driver, and the second driver has a convexly-shaped head to match the shape of the concavely-shaped anterior surface of the protrusive flange.

29. The device as claimed in claim 28, wherein the protrusive flange has a midpoint between opposing ends, and the concavely-shaped anterior surface thereof is an arc of a circle having its center at the temporomandibular joint of the user and a radius terminating at the midpoint or offset above or below the midpoint and defines an angle θ_1 relative to a free end of the opposing ends and defines an angle q_2 relative to an opposing end.

30. The device as claimed in claim 29, wherein θ_1 and q_2 are a combination of angle values that sum to 30 degrees, and the midpoint is approximately at a point where the mandible is open 13 degrees.

31. The device as claimed in claim 29, wherein θ_1 and q_2 are in a range of 12 to 15 degrees, and θ_1 is greater than q_2.

32. The device as claimed in any of claims 24 to 31, wherein the protrusive flange has a bend that orients the free end thereof generally toward the posterior and the second driver has a head shaped to fit the shape of the posterior side of the protrusive flange.

33. The device as claimed in any of claims 224 to 32, wherein the protrusive flange is releasably attachable to the housing of the mandibular piece.

34. The device as claimed in any of claims 24 to 33, wherein each power source is a rechargeable battery and each housing has a charging member in an exterior surface thereof.

35. A lingual repositioning device comprising:

a mandibular piece having a teeth covering having a left molar portion and/or a right molar portion and a housing proximate one or both of the left molar portion and the right molar portion;

wherein each housing includes a stimulator protrusion extending laterally inward to contact a lingual muscle of a user's tongue;

wherein each stimulator protrusion encloses an electrode and one or more sensors, and each housing encloses a power source electrically connected to an on-board circuit board and the on-board circuit board is operatively connected to the electrode and the one or more sensors;

wherein each on-board circuit board includes a receiver, a transmitter, and a microprocessor having instructions stored in nontransitory memory to activate the electrode based on data received from the one or more sensors as needed.

36. A maxillary device comprising:

a housing connectable to a tooth of a user or connectable or integral with a teeth covering, wherein the housing encloses an on-board circuit board and a power source and comprises a tooth connecting portion, and a palate housing portion and/or a buccal housing portion extending from the tooth connecting portion,

wherein each of the palate housing portion and the buccal housing portion encloses therein a stimulator having an electrode electrically connected to the on-board circuit board and the power source, and the palate portion and/or the buccal portion each enclose one or more sensors in electrical communication with the on-board circuit board;

wherein the on-board circuit board includes a receiver, a transmitter, and a microprocessor having instructions stored in nontransitory memory to activate one or both electrodes based on data received from the one or more sensors as needed based to stimulate a preselected muscle in contact with the palate portion or the buccal portion.

37. The device as claimed in claim 36, comprising a teeth covering having a left molar portion and/or a right molar portion, wherein the tooth connecting portion of the housing is connected to or integral with the teeth covering.

38. The device as claimed in claims 35 or 36, wherein the housing is removably attachable to the teeth covering.

39. The device as claimed in claim 38, wherein the teeth covering is a bite and mold disposable plastic teeth covering.

40. The device as claimed in claim 38, wherein the first housing is slidably received on the teeth covering or has a snap fit to the teeth covering.

41. The device as claimed in any of claims 24 to 41, wherein the one or more sensors are selected from the group consisting of a pulse oxygen sensor, a vibration and airflow sensor, a pH sensor, a doppler ultrasound sensor, an M-Mode ultrasound sensor, a 2D ultrasound sensor, 3D ultrasound sensor, a pressure plate sensor for measuring bruxism, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, and a cardiac trans-oral echocardiography sensor.

42. The device as claimed in any of claims 24 to 41, comprising a medicament dispenser in electrical communication with the microprocessor of a selected one of the on-board circuit boards; wherein the selected on-board circuit board receives data from the one or more sensors and activates the medicament dispenser to dispense a medicament to a user's oral cavity.

43. The device of claim 42, wherein the medicament dispenser is housed in either the stimulator protrusion or the palate housing portion when present and has a dispenser head open or openable for communication with the oral cavity.

44. A mandibular device comprising:

a first housing connectable to a tooth of a user or connectable or integral with a teeth covering, wherein the housing encloses an on-board circuit board and a power source and comprises a tooth connecting portion and a sublingual portion extending from the tooth connecting portion,

wherein the sublingual portion encloses one or more sensors and a medicament dispenser each of which are in electrical communication with the microprocessor of the on-board circuit board;

wherein the on-board circuit board receives data from the sensor and activates the medicament dispenser to dispense a medicament to a user's oral cavity based on data from the sensor.

45. The device as claimed in claims 42 to 44, wherein the medicament dispenser includes a reservoir housing one or more doses of the medicament.

46. The device as claimed in claim 45, wherein the medicament is a pellet, tablet, powder, or liquid.

47. The device as claimed in claim 45, wherein the medicament is nitroglycerin and the one or more sensor is a pulse oxygen sensor, a pulse transit time sensor, non-invasive ventilation systolic/diastolic blood pressure sensor, a carotid doppler (trans-oral) sensor, or a cardiac trans-oral echocardiography sensor

48. The device as claimed in any of claims 24 to 47, wherein each power source is a rechargeable battery and the each housing has a charging member in an exterior surface thereof that is in electrical communication with the rechargeable battery housed with its respective housing.

49. A mandibular and/or lingual repositioning system comprising:

a device from any of the preceding claims; and

a controller station in wireless communication with the device while used by a user, the controller station comprising:

a circuit board comprising a microprocessor, a receiver, and a transmitter, wherein the microprocessor comprises non-transitory memory having firmware and learning algorithms stored therein;

wherein the receiver receives data from the one or more sensors, while used by the user, and the microprocessor of the controller station processes the data and transmits activation instructions to each microprocessor of each on-board circuit board.

50. The system as claimed in claims 49, wherein the receiver and transmitter of the controller station communicate with a database of a physician, the Internet, a personal electronic communication device and combinations thereof.

51. The system as claimed in claims 49 or 50, wherein the controller station includes input and output ports for electrical interconnection to a power source and/or other electronic devices.

52. The system as claimed in any of claims 49 to 51, wherein the controller station comprises a first charging unit for the mandibular piece and a second charging unit for the maxillary piece.

53. The system as claimed in any of claims 49 to 52, wherein the controller station includes a display screen.

54. The system of claim 54, wherein the device is the mandibular lingual repositioning device according to claim 24; and the microprocessor of the controller station processes the data and transmits movement instructions to each microprocessors of each on-board circuit board in each housing of the mandibular lingual repositioning device, thereby directing the cranial to caudal adjustments, the anterior to posterior adjustments, and activation of the stimulator.

55. The system as claimed in claim 34, wherein the controller station directs the cranial to caudal adjustments, the anterior to posterior adjustments, and activation of the stimulator to be simultaneous, independent, or sequential.

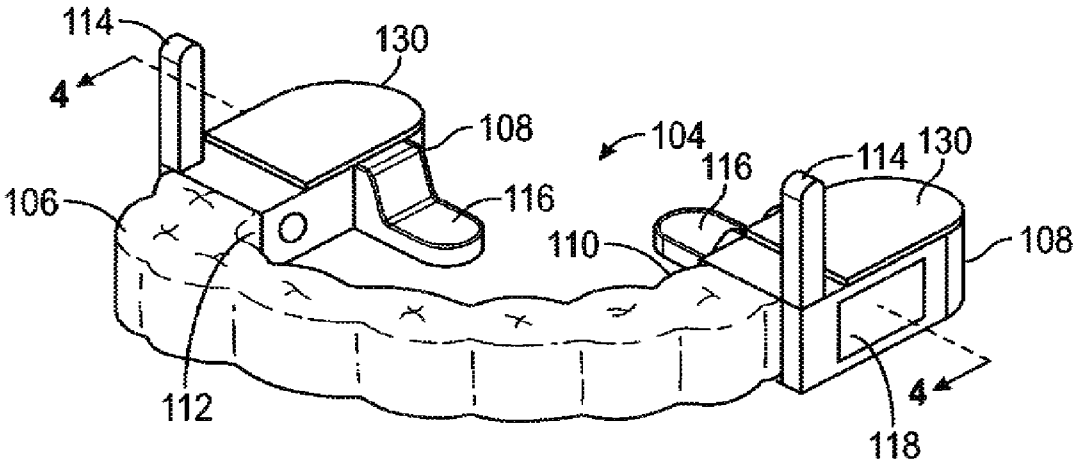
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FIG. 1

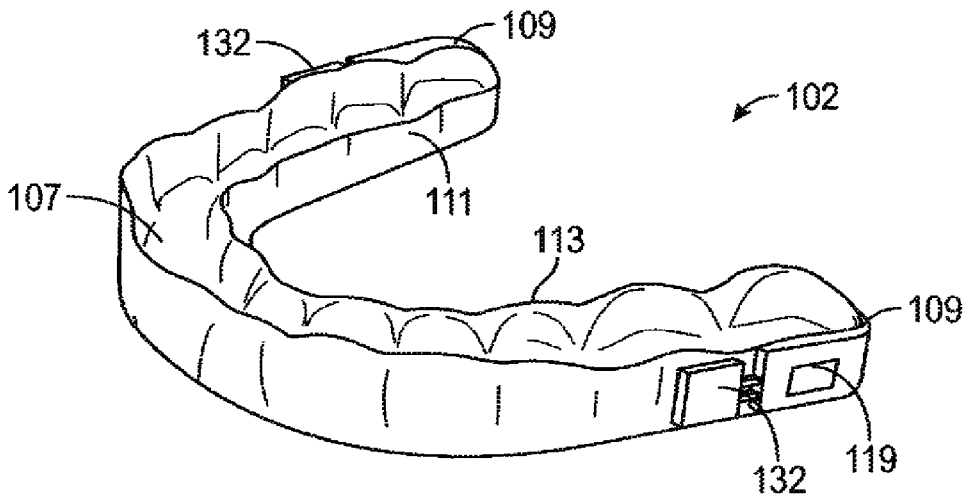
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FIG. 2

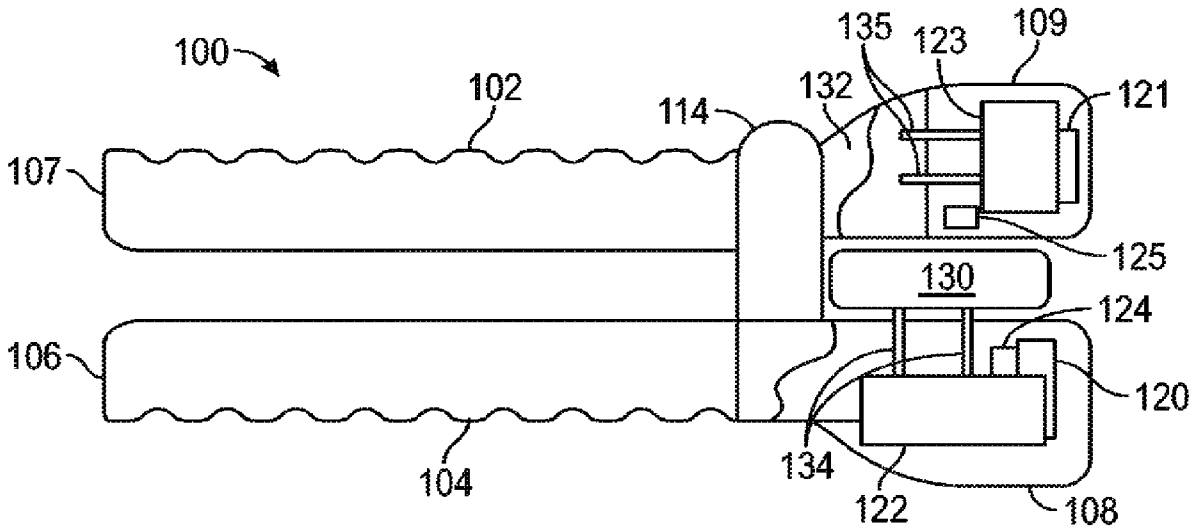
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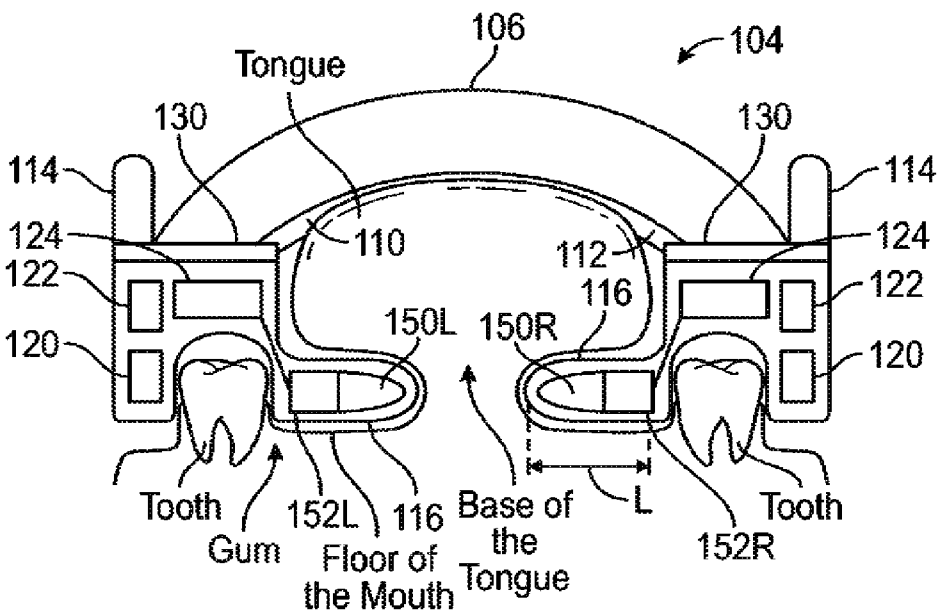
FIG. 3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130
114
114
124
124
110
112
122
116
122
150L
150R
120
120
Tooth
Gum
152L
116
Floor of the Mouth
Base of the Tongue
L
Tooth
152R

FIG. 4

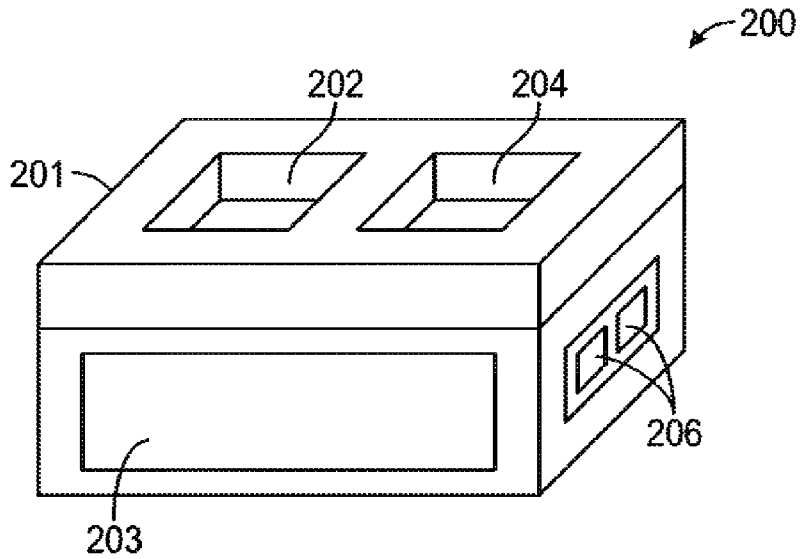

FIG. 5

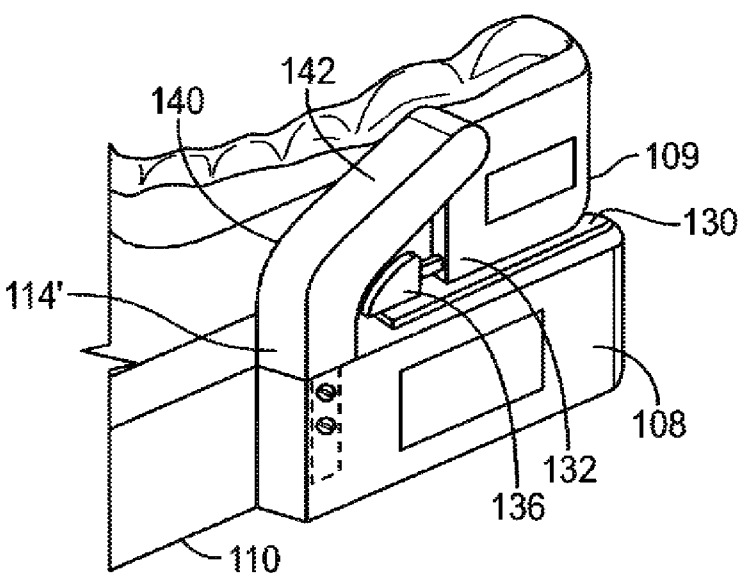

FIG. 6

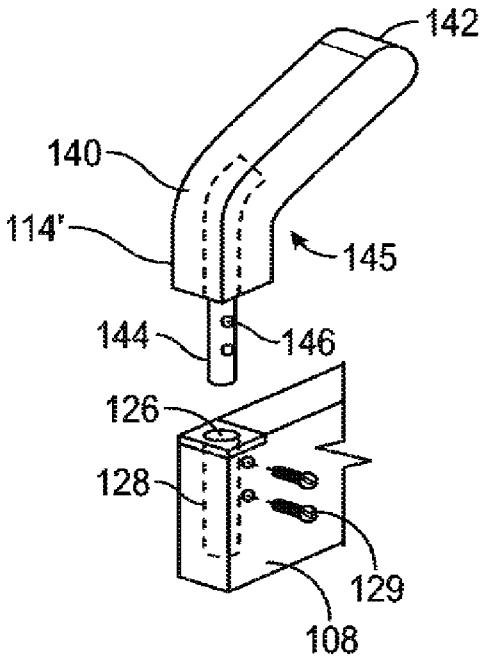
142
140
114'
145
144
146
126
128
129
108

FIG. 7

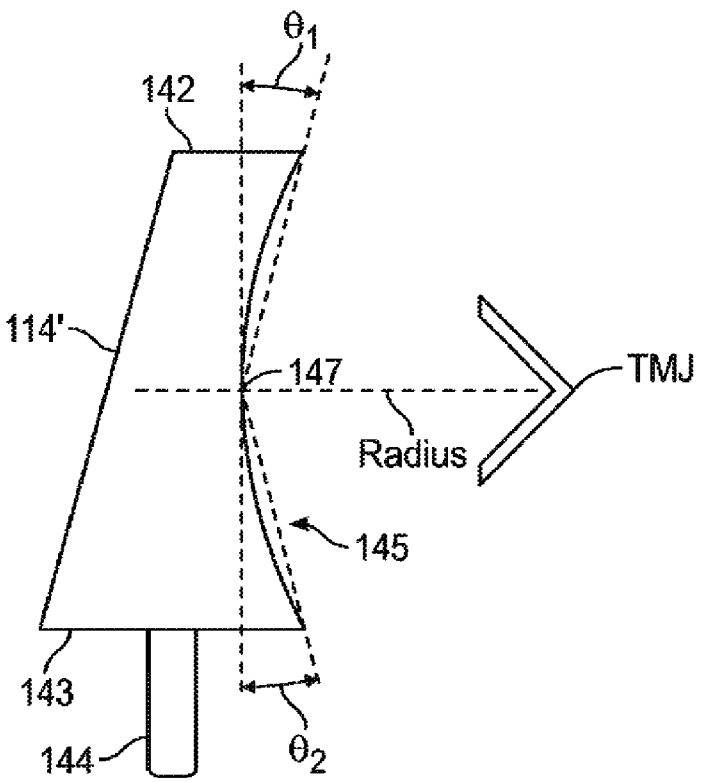
θ1
142
114'
147
TMJ
Radius
145
143
144
θ2

FIG. 8

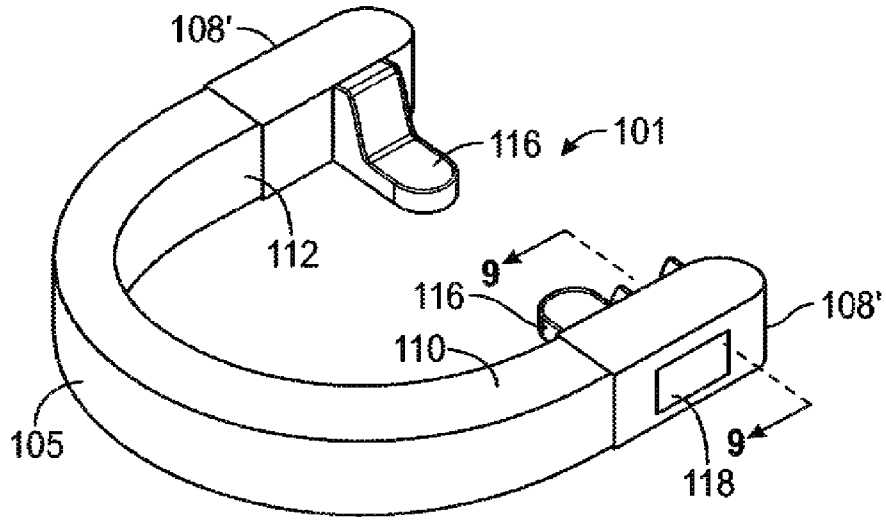
108'
116
101
112
9
116
108'
110
105
9
118

FIG. 9

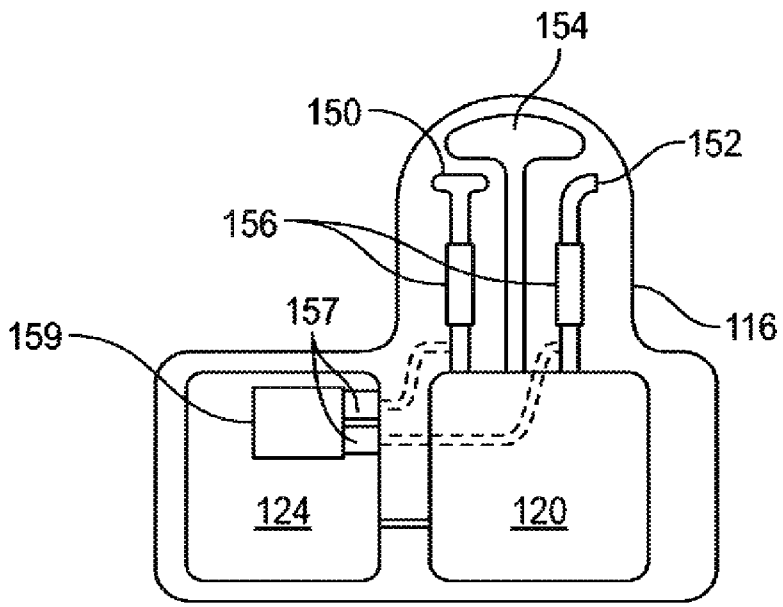
154
150
152
156
157
116
159
124
120

FIG. 10

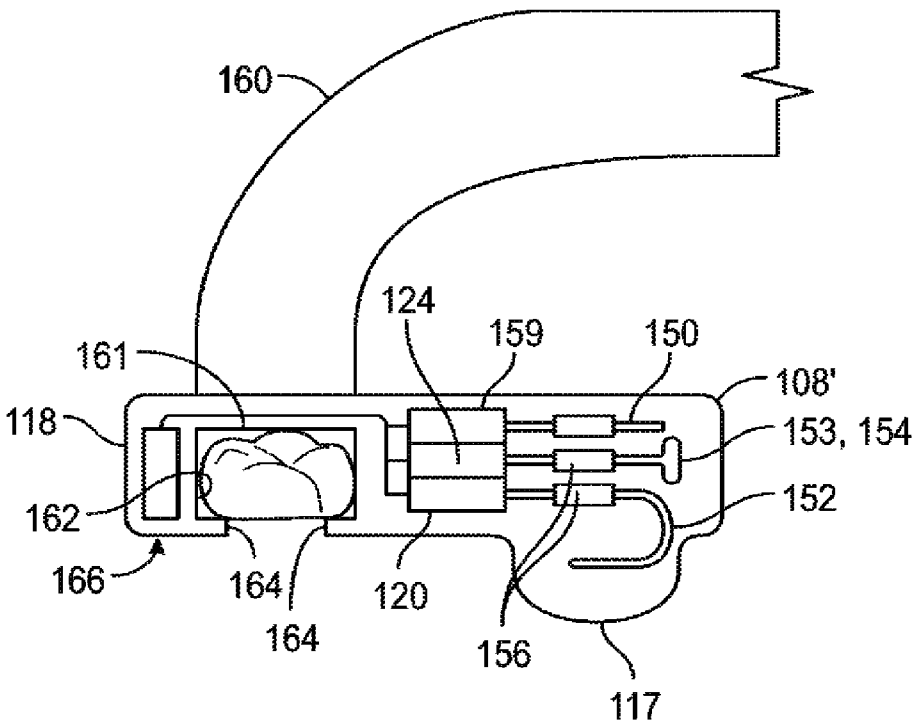
160
124
159
150
161
108'
118
153, 154
152
162
166
164
164
120
156
117

FIG. 11

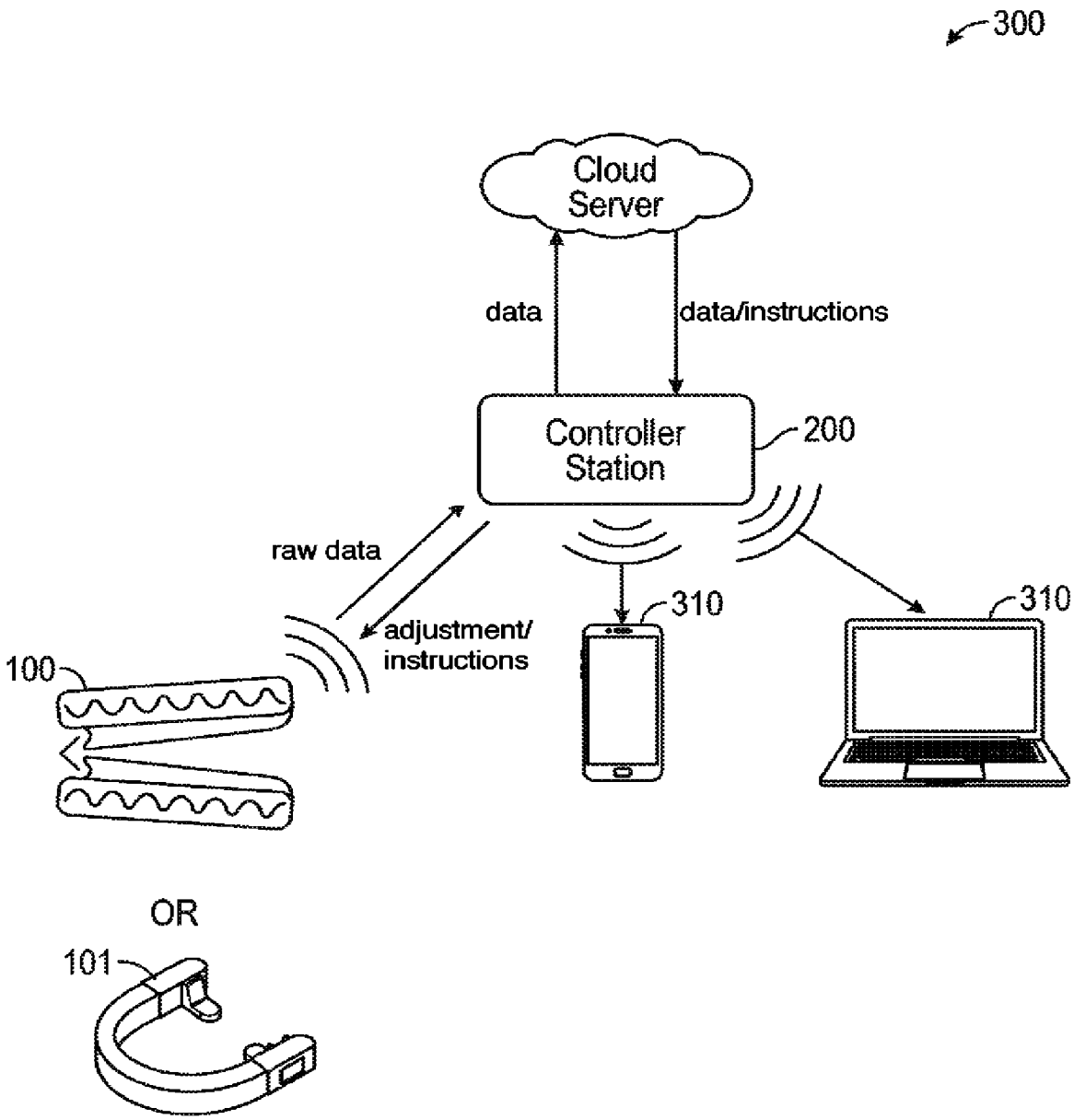
300
Cloud Server
data
data/instructions
Controller Station
200
raw data
adjustment/ instructions
310
310
100
OR
101

FIG. 12

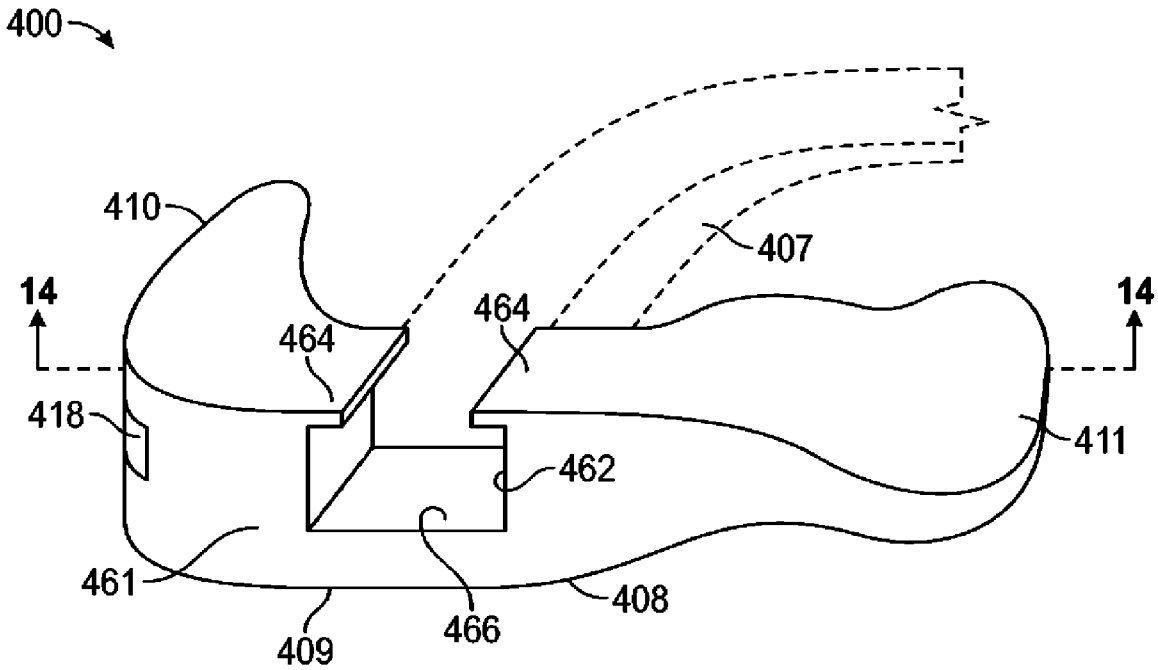
400
410
407
14
14
464
464
418
462
411
461
408
409
466

FIG. 13

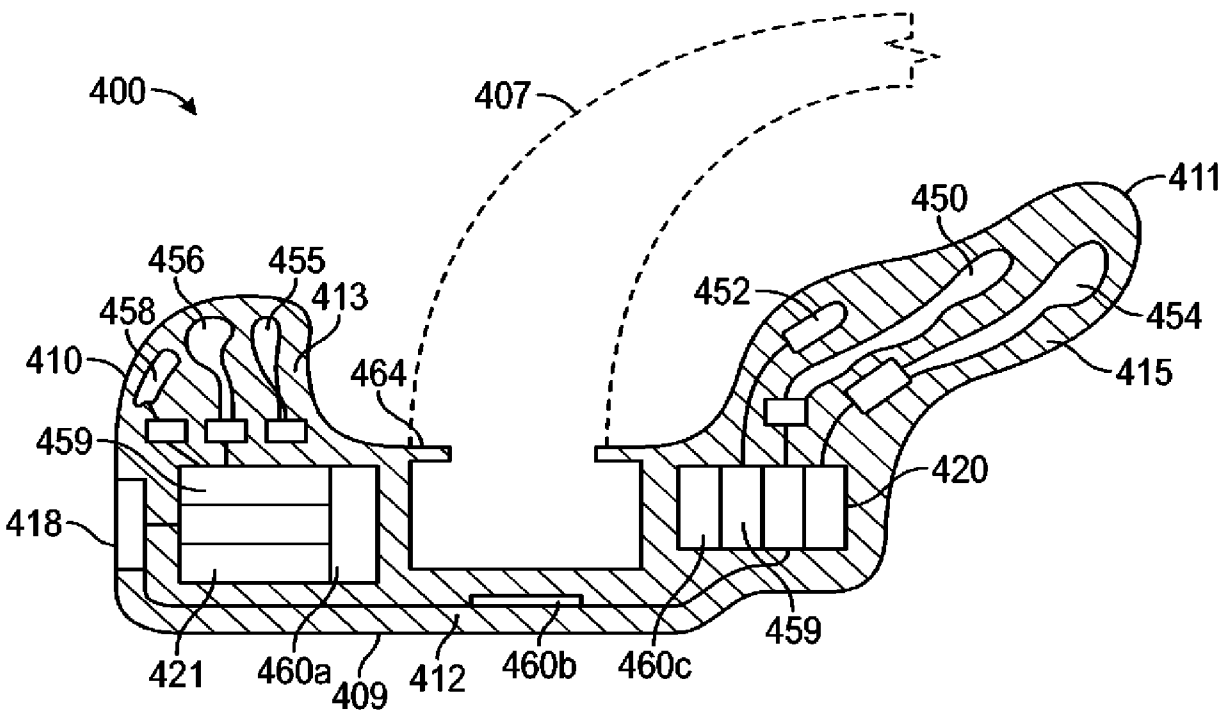
400
407
411
450
456
455
458
413
452
454
410
464
415
459
420
418
459
421
460a
409
412
460b
460c

FIG. 14

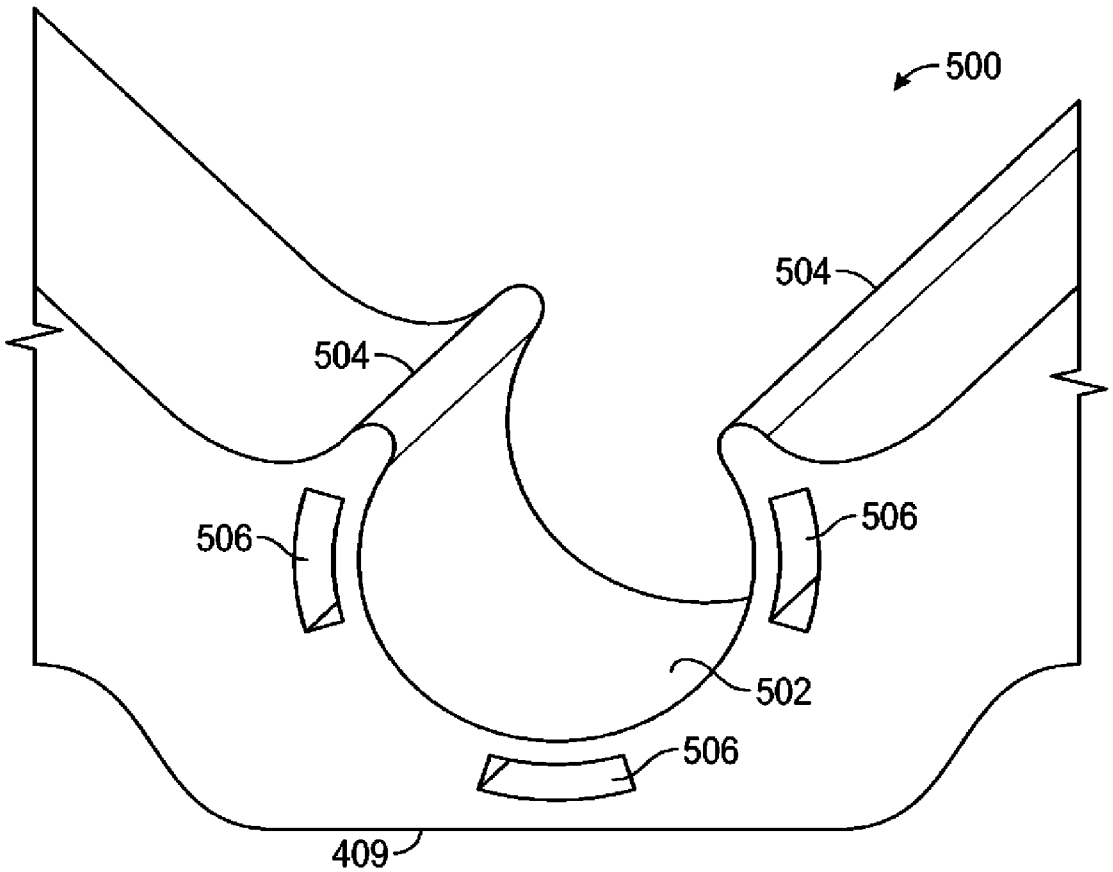
500
504
504
506
506
502
506
409

FIG. 15

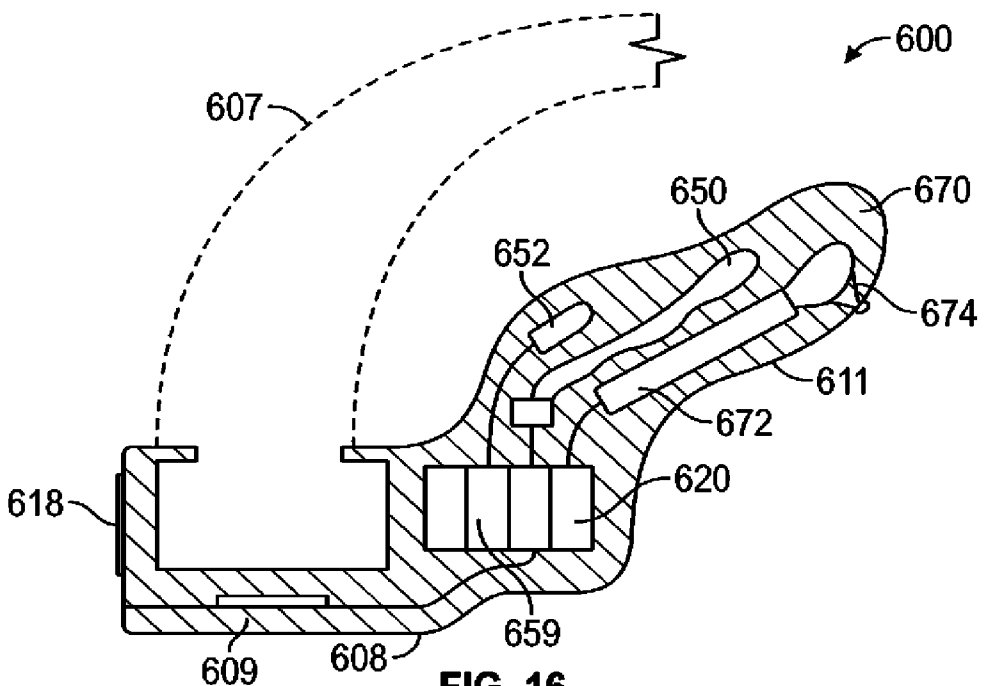
600
607
650
670
652
674
611
672
620
618
659
609
608

FIG. 16

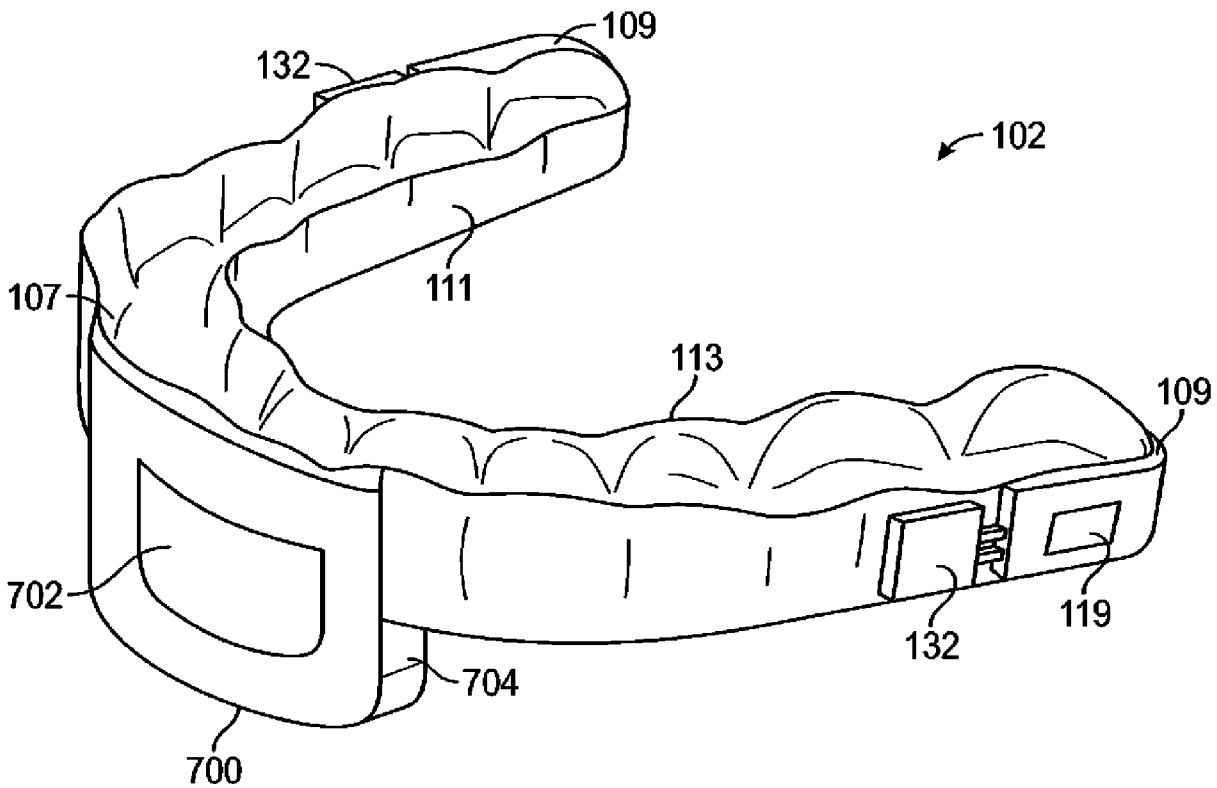

FIG. 17

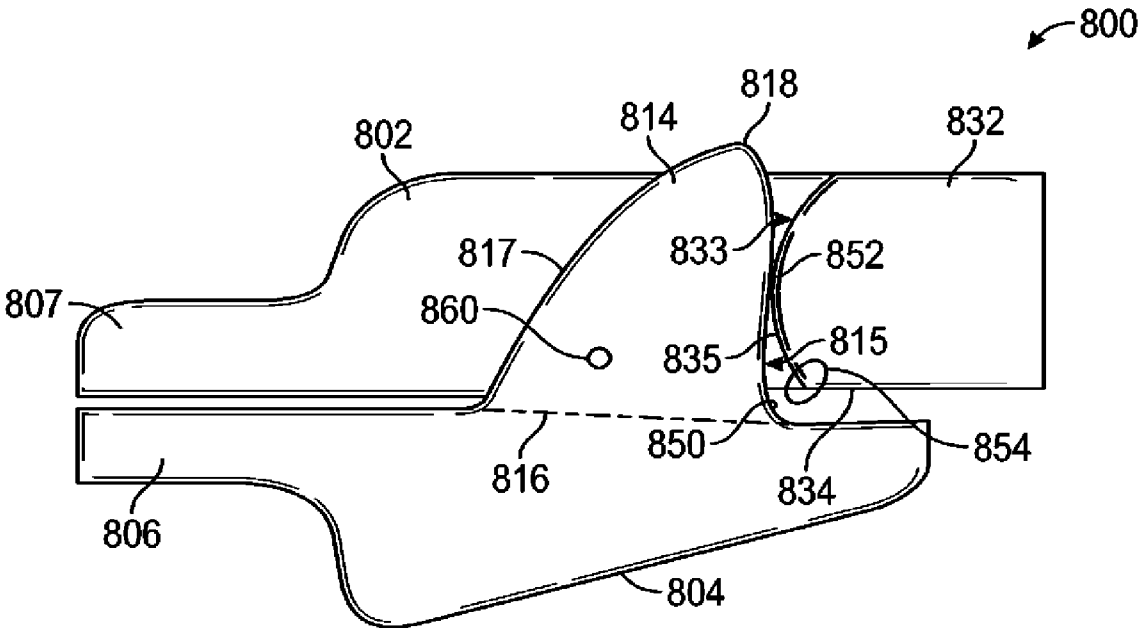
800
818
814
802
832
817
833
852
807
860
835
815
850
854
816
834
806
804

FIG. 18

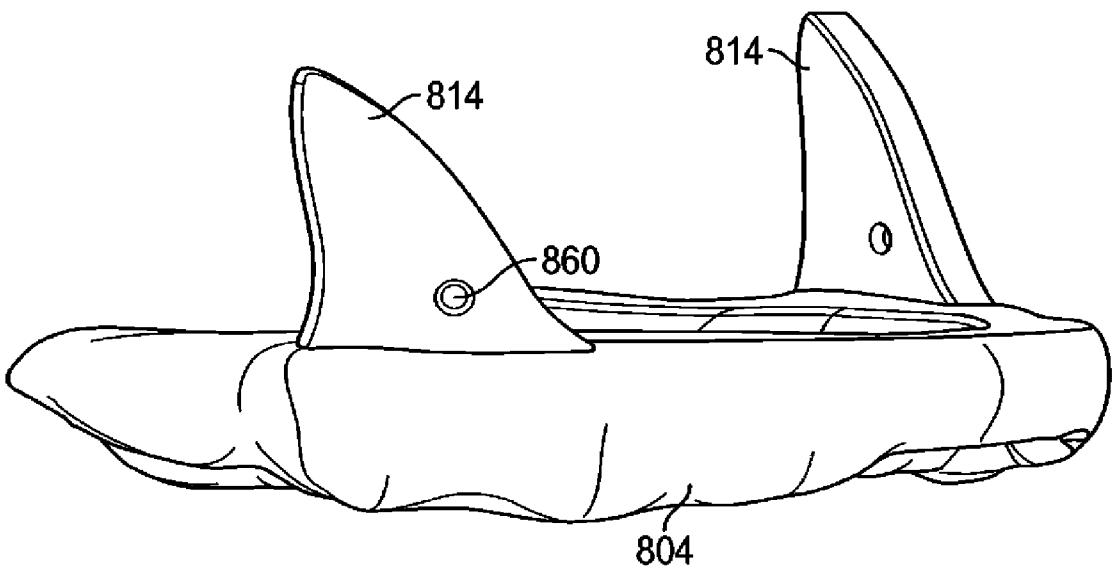
814
814
860
804

FIG. 19

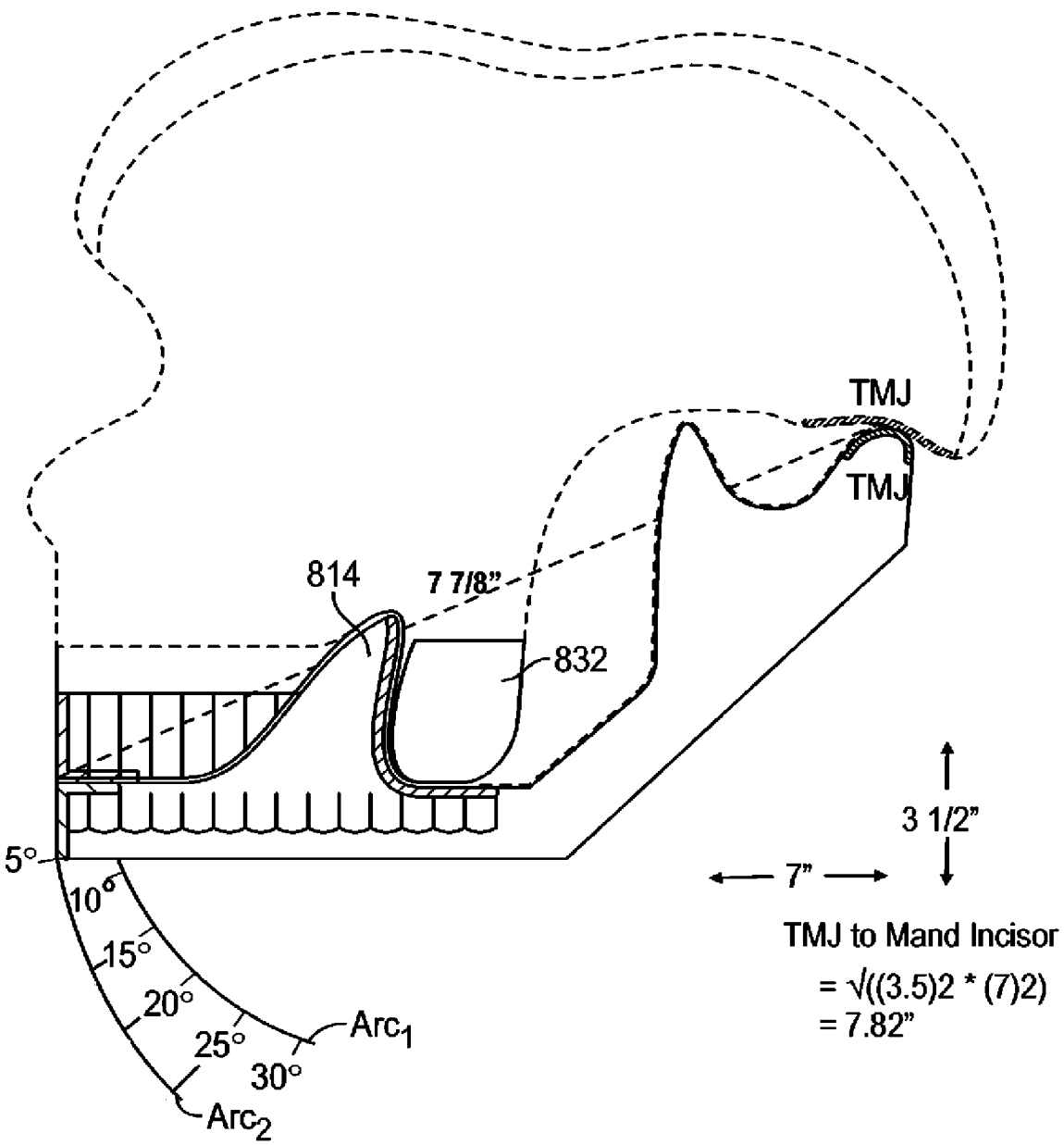
Scale 1 in = 10 mm
TMJ
TMJ
814
7 7/8"
832
3 1/2"
7"
5°
10°
15°
20°
25°
30°
Arc1
Arc2
TMJ to Mand Incisor
= √((3.5)2 * (7)2)
= 7.82"

FIG. 20

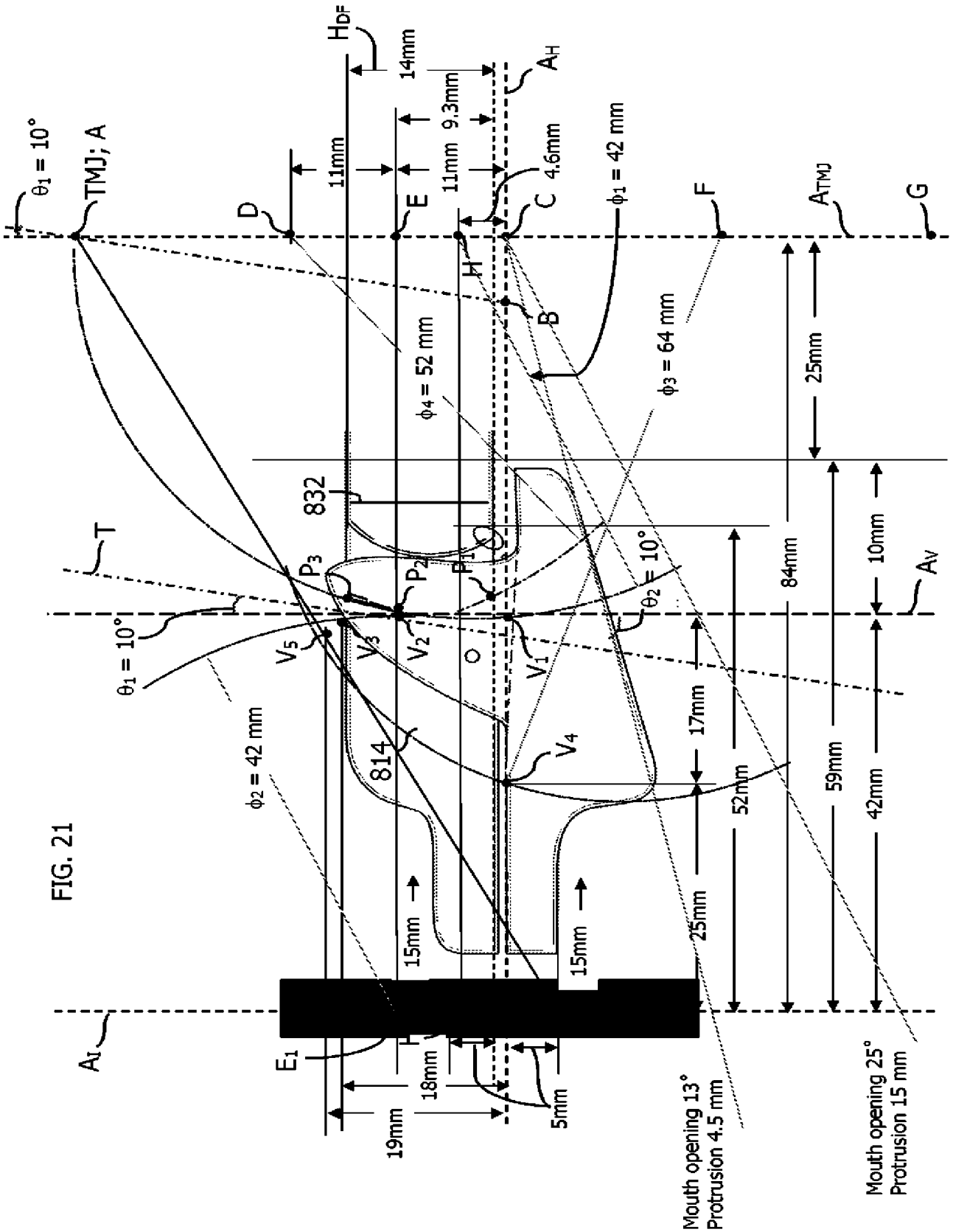

FIG. 21

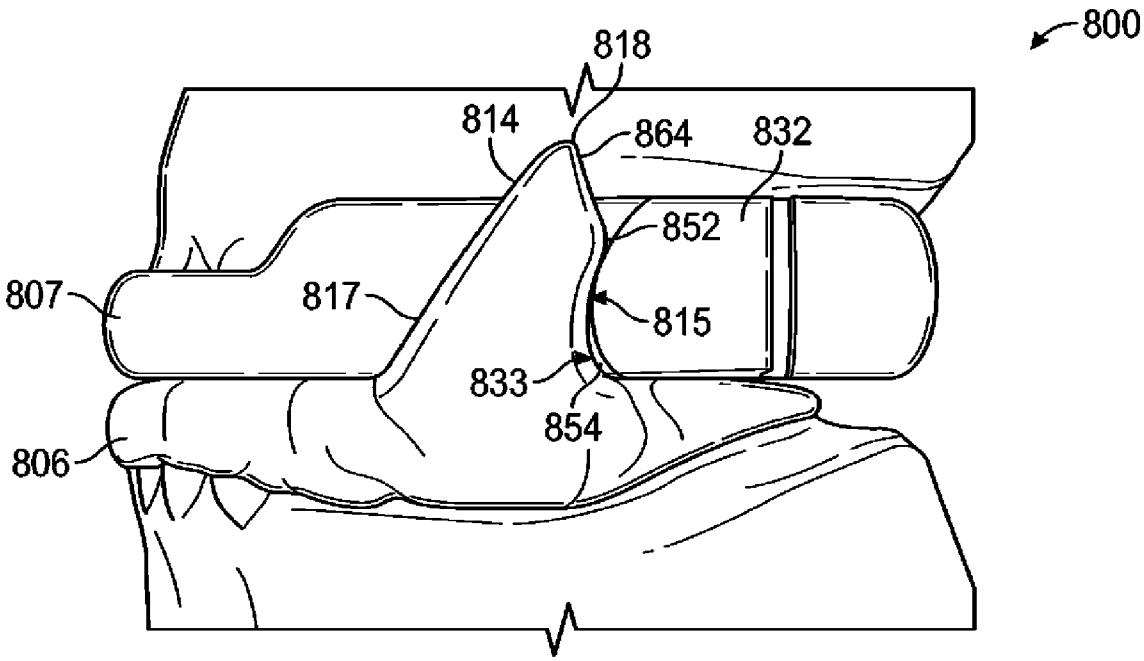

FIG. 22

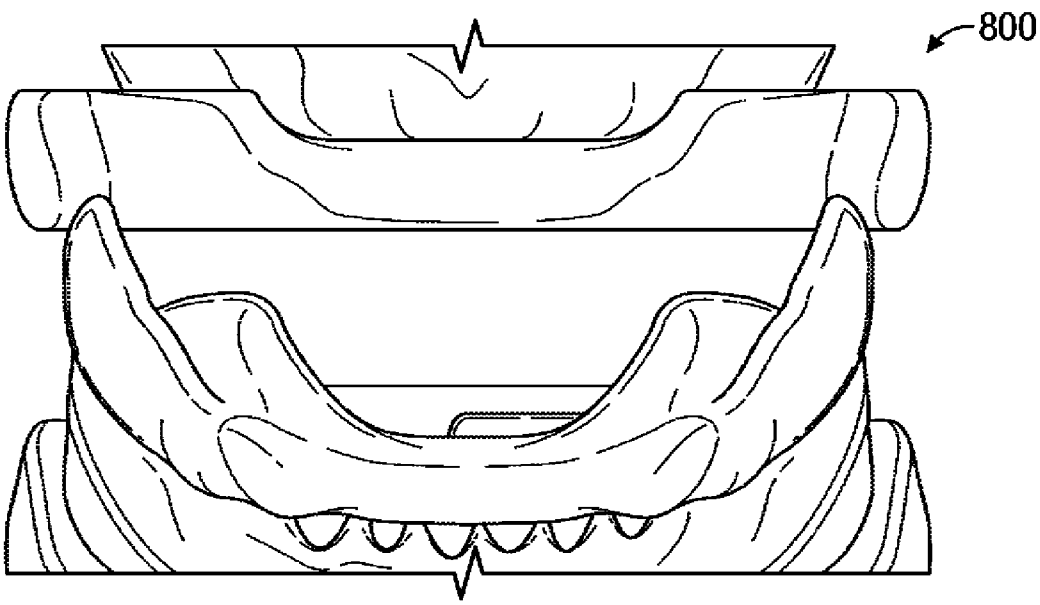

FIG. 23