

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
9 December 2010 (09.12.2010)

(10) International Publication Number
WO 2010/141220 A1

(51) International Patent Classification:
A61F 5/56 (2006.01)

(21) International Application Number:
PCT/US2010/035414

(22) International Filing Date:
19 May 2010 (19.05.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12/476,872 2 June 2009 (02.06.2009) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,

HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report (Art. 21(3))

(54) Title: METHOD AND APPARATUS FOR TREATING SLEEP APNEA

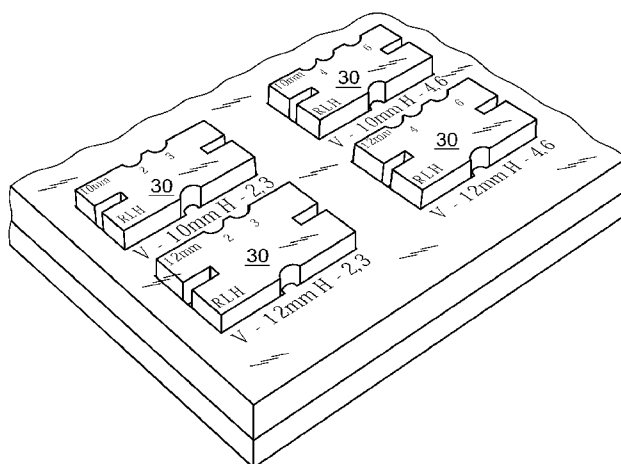


FIG. 5

(57) Abstract: A method and apparatus for diagnosing sleep apnea and for comfortably fitting an oral device to treat the condition. The patient is screened to reduce snoring using a device which changes the airway, and then using an airway dilation simulator having sequentially sized elements to determine the mandibular position maximizing the upper airway dimension. An oral device is then fabricated to retain the maximum position during sleep.

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Description

METHOD AND APPARATUS FOR TREATING SLEEP APNEA

Technical Field

[0001] This invention relates to sleep apnea, and more particularly, to an apparatus for diagnosing and treating sleep apnea, including the method of measuring the airway with the mandible in precisely displaced positions until the airway allows a maximum airflow within the comfort zone of the patient, and then fabricating an appliance to maintain the mandibular position during sleep.

Background of the Invention

[0002] Although sleep apnea has been recognized as a critical life-endangering problem, there are still a limited number of doctors or dentists trained to treat this disorder and a limited number of treatments. The traditional options for treating obstructive sleep apnea, which is a medical condition where there is a blockage of the airway usually caused by the soft tissue in the rear of the throat, which collapses and closes during sleep, are with the nasal continuous positive air pressure (nCPAP), an oral airway dilator or with surgery. The treatments using positive air pressure and the oral airway dilators (OAD) are not cures, but reversible management tools.

[0003] Some of the common design features in the first generation (OADs) airway dilator resulted in minimal success and gave them a negative image in sleep medicine. The current designs of the OADs have increased their successes, and they are now more widely accepted for managing sleep apnea and are far more user-friendly and socially acceptable.

[0004] The current CPAPs on the market are expensive, difficult to adjust and largely uncomfortable, and therefore disagreeable to the patient during the diagnosis and fitting process. Further, a percentage of these devices are non-compliant.

[0005] Current publications which are not necessarily directly related to sleep apnea but may be considered prior art to the current invention include:

[0006] U.S. Patent No. 1,800,714 granted to Clapp April 14, 1931, which discloses a stepped device for determining the particular bite when artificial dentures are needed, and the device includes a scale intended to measure the angle of a line drawn from the crest of the upper edentulous ridge to the crest of the lower edentulous ridge.

[0007] U.S. Patent No. Re 23,442 granted to George November 20, 1990, teaches the use of an appliance designed to prevent the occlusion of the oro-pharyngeal airway, which includes a front beak.

[0008] U.S. Patent No. 4,997,368 granted to Mayer *et al* March 5, 1991, discloses an oral measuring device for determining the size of the mouth opening and the range of motion to determine the success or nature of the operation performed following facial or oral surgery.

[0009] U.S. Patent No. 5,154,609 granted to George October 15, 1992, discloses an instrument including calibrations and extensions for registration of the dental bite of a patient, and includes as a combination a bite fork.

Disclosure of the Invention

[0010] With the above-noted prior art and inadequacies in mind, it is the goal of the present invention to provide a simple, straightforward diagnostic tool for obstructive sleep apnea, as well as a simple, accurate tool for determining the optimal position of the mandibular to maximize the air flow while not compromising the comfort of the patient. The diagnostic tool allows the dental personnel to quickly measure the position of the patient's lower jaw when maximizing the air flow to determine the suitability of the possible use of an oral airway dilator.

[0011] The airway dilution simulator comprises a plurality of sequentially sized elements for positioning the mandible as guided by the patients' subjective feedback on their airway changes and comfort. The utilization of the present invention also quickly interfaces with acoustic reflection pharyngometry that measures the upper airway dimension in any of the

mandibular positions with this invention, thus permitting the dental personnel to determine the position for maximum air flow.

[0012] Following the determination of maximum airway dimension, the dental personnel can fabricate an oral device to retain the mandible in the optimal position during sleep. The process of achieving the optimal position of the mandible may take more than one measurement and more than one adjustment, spread out over a period of time, to allow the patient to comfortably adjust to the proscribed changes.

Brief Description of the Drawings

[0013] Figure 1 is an elevational view of the snoring/airway screener.

[0014] Figure 2 is a side elevational view of one of a series of airway dilation simulators.

[0015] Figure 3 is a plan view of the bite fork.

[0016] Figure 4 is an illustration of the portion of a set of a series of the airway dilation simulator as seen in Figure 2.

[0017] Figure 5 is an illustration of some of the representative apparatus in a storage case.

Best Mode for Carrying Out the Invention

[0018] As seen in Figure 1, the snoring/airway screener which empirically utilizes the snoring sound generated by the patient and is relatively low tech, but empirically shows a high correlation with the airway size in the airway segment that obstructive sleep apnea airway dilators falter. Therefore, it is an effective screening tool. The screener serves as a quick way to narrow the more definitive analysis zone for optimum airway flow. The system enables repeatability in any position.

[0019] Historically, after the standard muscle joint and range of motion screening, there were no devices or accepted techniques for predicting success with an oral airway dilator. Sonar technology has been adapted to measure the upper airway by sending an echo through the mouth and into the airway while the patient holds a snorkel-like mouthpiece between their teeth and

breathes naturally. This process is actually comfortable, cost-effective and also produces data and graphical output for analysis. This modality is called acoustic reflective pharyngometry, where the instrument effectively measures the status quo of the patient but nothing exists to show the pharyngometry to simulate jaw positions to determine whether they are a candidate for the oral airway dilator treatment and which device would be more effective.

[0020] The snoring/airway screener as shown in Figure 1, as noted hereinabove, is an effective screening tool for detecting airway dilator candidacy, having a high correlation with a pharyngometer. The device itself is a relatively thin piece of material which is sterilizable, having a bottom surface 2 calibrated, a rear surface 4 likewise calibrated, and a front surface 6 of a stair-step design, such that in use, the patient places his upper incisor on the desired step (as designated by the calibration) and moves the lower jaw to the position wherein the snore noise is least, giving the clinician the quick determination and accurate location indicating that this type of correction could and would be useful as a reference for further treatment and perhaps installation of an oral airway dilator.

[0021] As seen in Figure 2, one of the airway dilation simulators is shown. It comprises a relatively thin piece of material which is sterilizable and, as explained hereinafter, is shown as only one of a series of simulators that are used to allow the pharyngometer testing of the jaw and airway dimension in simulated positions. The simulator is a rectangular piece of material having a bottom 8, including an indentation 10 for the lower incisor, a top 12 having one or more indentations 14 for the placement of the upper incisor to selectively find the maximum air flow position through the sequential use of the set until the clinician determines which relative position maximizes the flow and least comprises comfort. The mandibular positioning simulator includes inscribed information telling the clinician precisely the relative location, vertical and horizontal, of the incisors to reduce the chance of error and permitting an accurate repetition of positions. The simulator includes two end portions 16 and 18, each including a slot 20-22 for reasons to be explained hereinafter.

[0022] Reference is now had to Figure 3, wherein an instrument, generally known as a bite fork, is shown, which includes a horseshoe-shaped main body portion 24 having a plurality

of spaced openings, and a rearwardly projecting mounting member 26 having an inwardly projecting slot 28.

[0023] As seen in Figure 4, the simulator as shown in Figure 2 is shown in conjunction with the fork of Figure 3, such that when the optimal relative jaw position both vertical and horizontal is determined using the simulator and the pharyngometer, then the fork is attached to the simulator. This provides the correct jaw position and a fitting substance is spread evenly on the fork so that the impression of the patient's teeth can be reproduced in the oral airway dilator, which is fabricated using the information achieved through the combination of the pharyngometer and the sequential use of the simulators.

[0024] Reference is now had to Figure 5, wherein there is shown a portion of a kit, including a plurality of the simulators 15 in a case. It is important to note that the simulators vary in height from 4 mm to 12 mm and the horizontal displacement of the lower mandible varies from 2 mm to 7 mm, allowing the clinician to place a series of the simulator in the mouth of the patient with or without the pharyngometer to determine the maximum and minimum discomfort as plotted on a graph. It is to be understood that the simulators are constructed such that they can be reversed as desired, thereby providing over 50 selected jaw positions.

[0025] Thus, as can be seen, the present invention provides a quick and simple, straightforward method and apparatus for a snoring/airway screener and a kit which allows the clinician to use the pharyngometer to determine airway dimensions, predicting air flow while noting the precise position, horizontally and vertically, of the mandibles.

[0025] Mandibular positioning system for optimum airway includes fifteen simulators which provide 40 horizontal and vertical combinations that enable bite registration in the selected position. Simulators, easily placed by patient, create simple, effective, repeatable, and predictable position for device effectiveness and quickly interface with pharyngometry. Accessories enable screening and device tuning.

[0026] Although a preferred embodiment of the invention has been disclosed for purposes of illustration, it should be understood that various changes, modifications and

substitutions may be incorporated in the embodiment without departing from the spirit of the invention, which is defined by the claims which follow.

What is claimed is:

Claims

1. A method of modifying the air passage of a person with sleep apnea, comprising the steps of:

reviewing the health history of the person;

making an objective evaluation of the person's snore factor;

displacing the lower jaw relative to the upper jaw vertically and horizontally by successive predetermined increments to maximize the air flow and minimize the discomfort; and

fabricate an appliance to secure the jaw in the optimal position while sleeping.

2. A method as in claim 1, wherein the jaw displacement could extend over more than one appointment.

3. A method as in claim 1, wherein the jaw displacement is accomplished with sequential use of discrete calibrated elements of a defined set of elements.

4. A method as in claim 3, and further including the step of temporarily securing a fork to the calibrated element to facilitate securing an impression of the teeth with the jaw in the selected optimal position.

5. A method of treating sleep disorders, comprising:
conduct a snore screening operation utilizing a screening instrument which allows precise and measurable manipulation of the lower jaw to maximize airflow;
precisely locate the lower jaw utilizing a series of jaw locator devices having fixed sequential horizontal and vertical tooth receiving and positioning notches until a comfortable position is found for the patient which maximizes the air flow.

6. A method as in claim 1, wherein the appliance for retaining the lower jaw position is molded in place at the comfortable position.

7. A set of tools for diagnosing and treating breathing disorders such as sleep apnea including a presorted set of discrete mandibular positioning elements including positioning means for upper and lower incisors controlling the relative vertical and horizontal position enabling comparative airway measurements.

8. A kit for determining and simulating the optimal airway dilation for a person having obstructive sleep apnea, comprising a plurality of similar rectangular elements having ends and sides, wherein each element includes opposing slots extending inwardly from the ends, each element contains a groove mid-point on one side and at least two grooves on the opposite side, said grooves determining the relative horizontal jaw position when the incisors are placed in the grooves, said elements further having predetermined end dimensions to control the relative vertical jaw position.

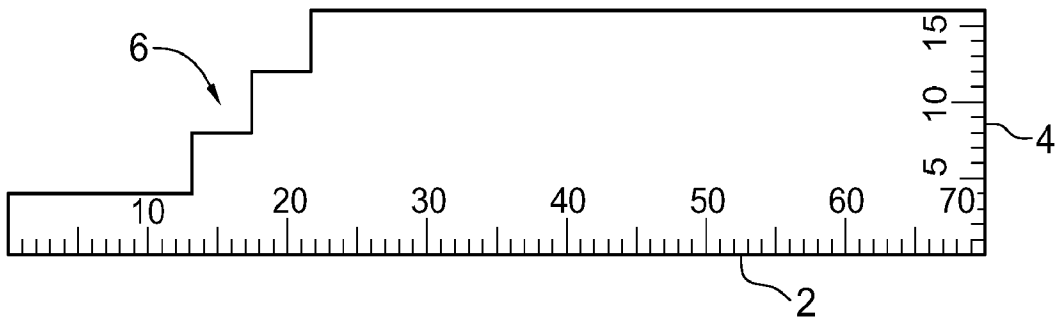


FIG. 1

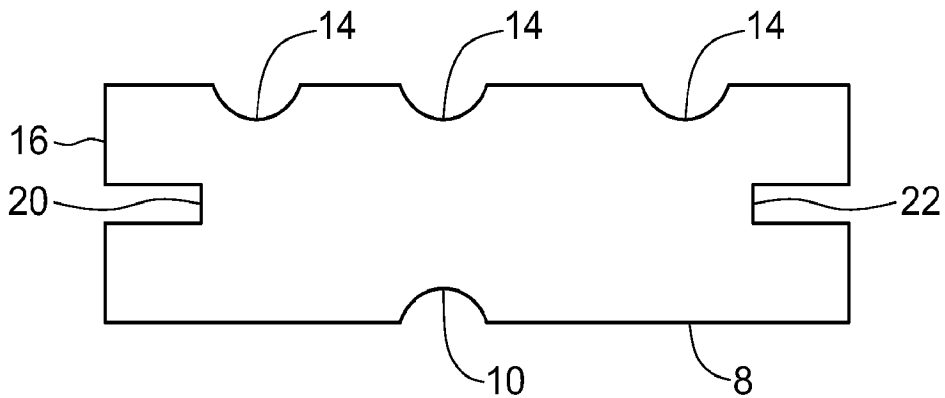


FIG. 2

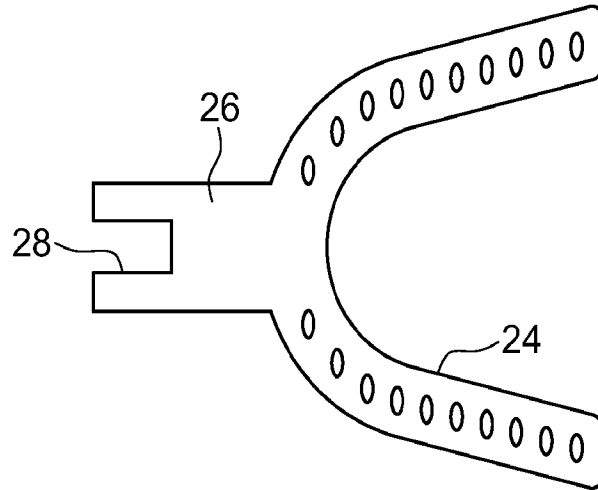


FIG. 3

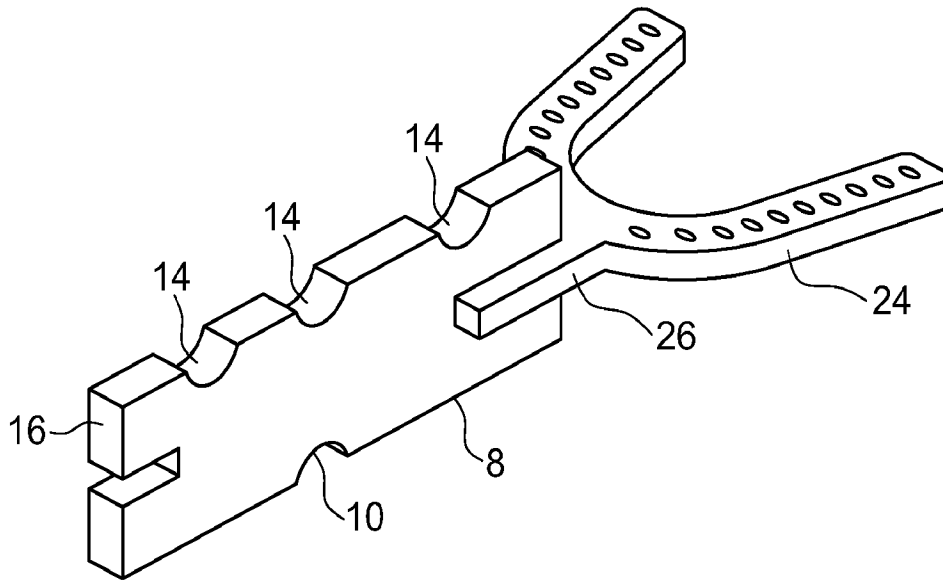


FIG. 4

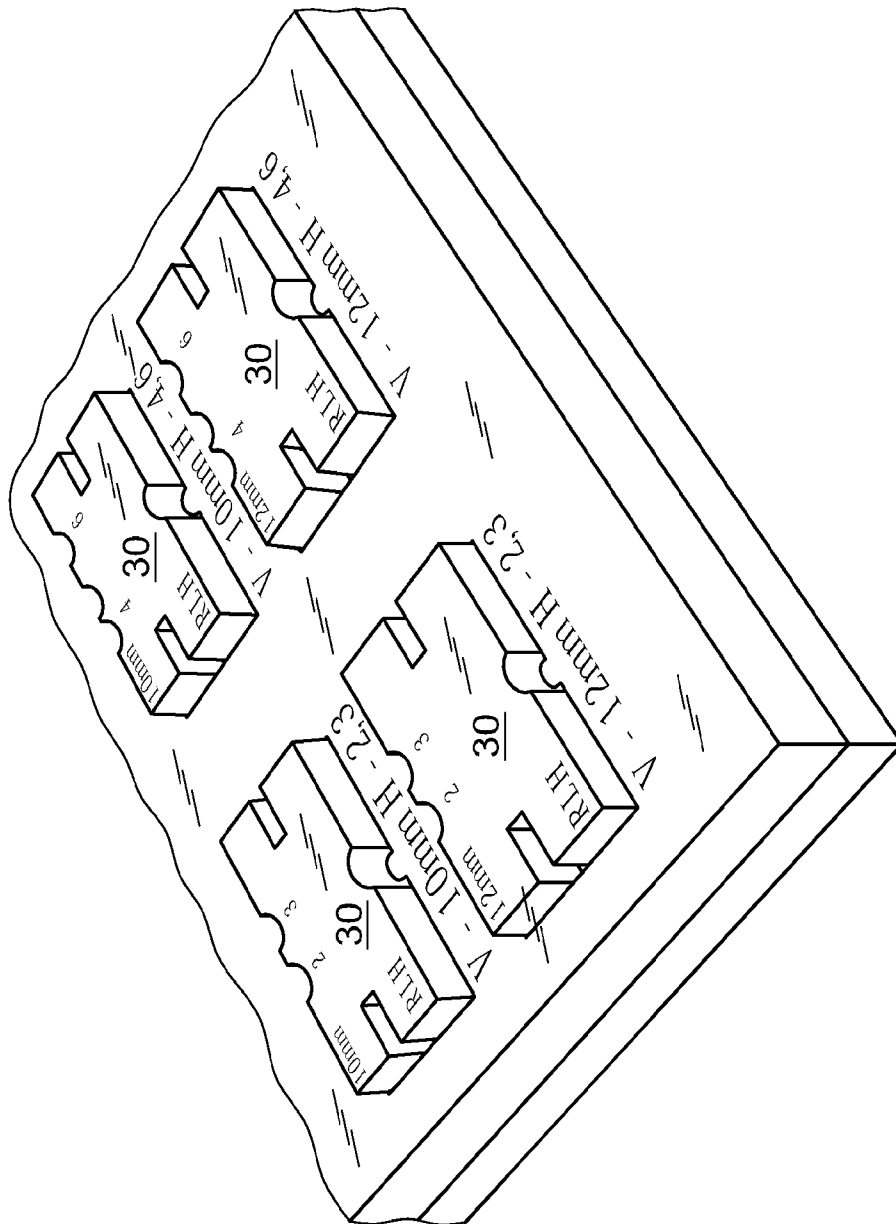


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/035414

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 5/56 (2010.01)

USPC - 128/848

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 5/56 (2010.01)

USPC - 128/848, 861; 602/902

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

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

PatBase, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,885,073 A (KUSSICK) 23 March 1999 (23.03.1999) entire document	5, 7

Y		1-4, 6, 8
Y	US 5,003,994 A (COOK) 02 April 1991 (02.04.1991) entire document	1-4, 6
Y	US 4,997,368 A (MAYER et al) 05 March 1991 (05.03.1991) entire document	8

 Further documents are listed in the continuation of Box C.


* Special categories of cited documents:

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

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

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

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

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

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

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Date of the actual completion of the international search

16 June 2010

Date of mailing of the international search report

20 JUL 2010

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