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Remmers et al.

(10) **Patent No.: US 10,195,070 B2**
(45) **Date of Patent: Feb. 5, 2019**

(54) **METHODS AND APPARATUSES FOR PERFORMING REMOTE TITRATION OF MANDIBULAR PROTRUSION**

(52) **U.S. Cl.**
CPC *A61F 5/566* (2013.01); *A61B 5/1072* (2013.01); *A61B 5/14542* (2013.01);
(Continued)

(71) Applicant: **ZST HOLDINGS, INC.**, Calgary (CA)

(58) **Field of Classification Search**
CPC .. *A61F 5/566*; *A61F 5/556*; *A61B 2560/0228*; *A61B 5/4812*
See application file for complete search history.

(72) Inventors: **John Remmers**, Sedona, AZ (US);
Hugo Tam, Calgary (CA); **Terry Macartney**, Calgary (CA); **Peter Santosham**, Calgary (CA); **Zbigniew Ludwik Topor**, Calgary (CA); **Joshua Grosse**, Calgary (CA)

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(73) Assignee: **ZST HOLDINGS, INC.**, Calgary (CA)

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(21) Appl. No.: **14/407,194**

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(Continued)

§ 371 (c)(1),
(2) Date: **Dec. 11, 2014**

(87) PCT Pub. No.: **WO2013/188660**

Primary Examiner — Lynsey C Eiseman
Assistant Examiner — Amanda L Steinberg
(74) *Attorney, Agent, or Firm* — Meunier Carlin & Curfman LLC

PCT Pub. Date: **Dec. 19, 2013**

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(57) **ABSTRACT**

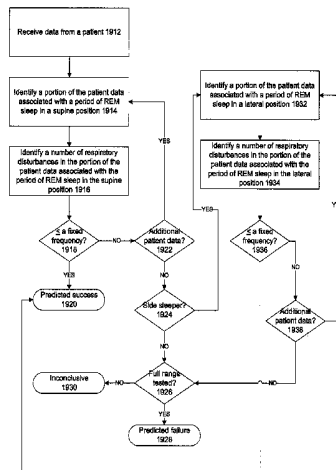
Related U.S. Application Data

Methods and apparatus for performing system validation and providing predictive criteria during remote titration of mandibular protrusion are disclosed herein. The effectiveness of oral appliance therapy can possibly be improved by screening obstructive sleep apnea subjects and prospectively identifying subjects suitable for oral appliance therapy. The methods and apparatus for performing system validation on an oral appliance therapy titration system are disclosed. In addition, methods and apparatus for providing predictive (Continued)

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(51) **Int. Cl.**
A61B 5/00 (2006.01)
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(Continued)



criteria during remote titration of mandibular protrusion are disclosed. Further, methods and apparatus for display results of remote titration of mandibular protrusion are disclosed.

26 Claims, 27 Drawing Sheets

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A61B 5/107 (2006.01)
A61B 5/145 (2006.01)
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(52) **U.S. Cl.**

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 (2013.01); *A61B 5/742* (2013.01); *A61B*
5/1116 (2013.01); *A61B 5/14551* (2013.01);
A61B 2560/0228 (2013.01)

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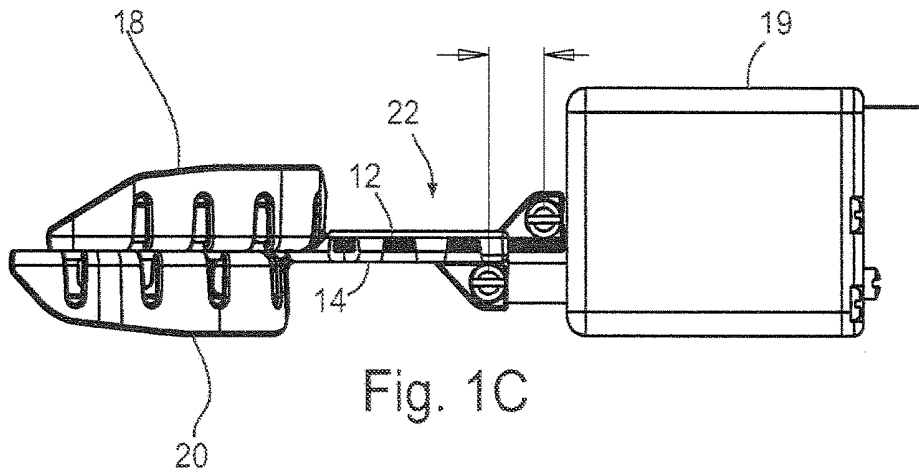
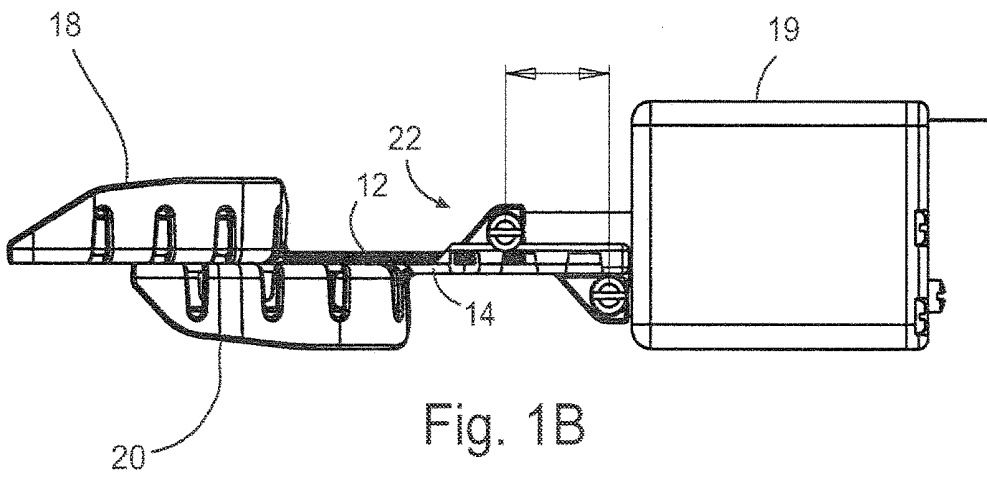
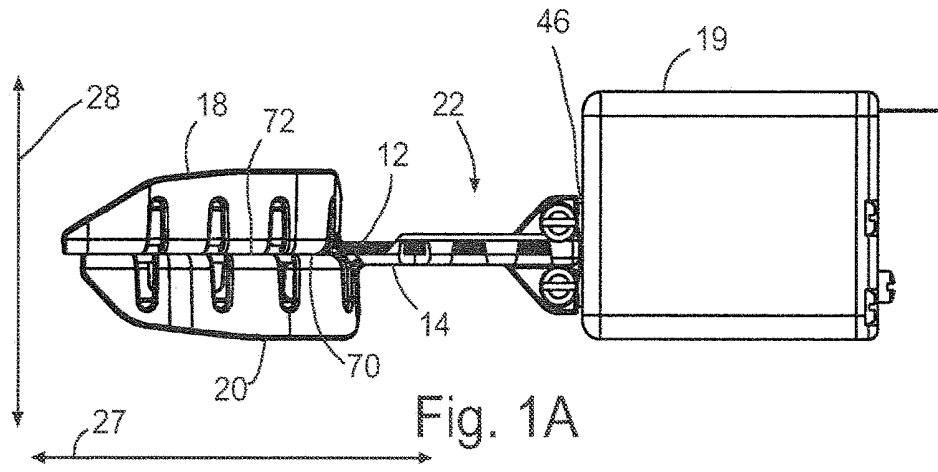
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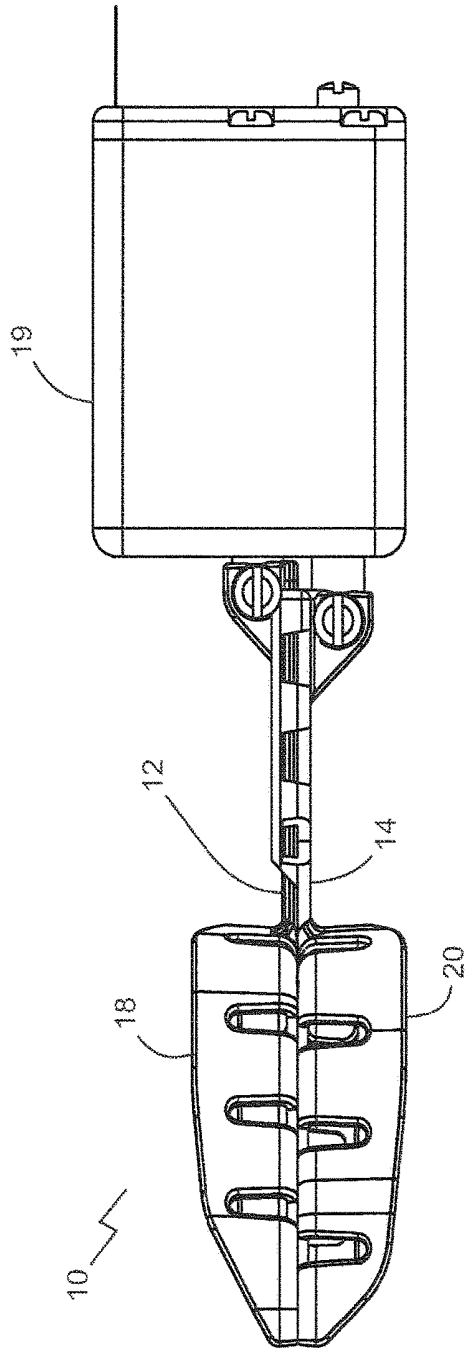


Fig. 2

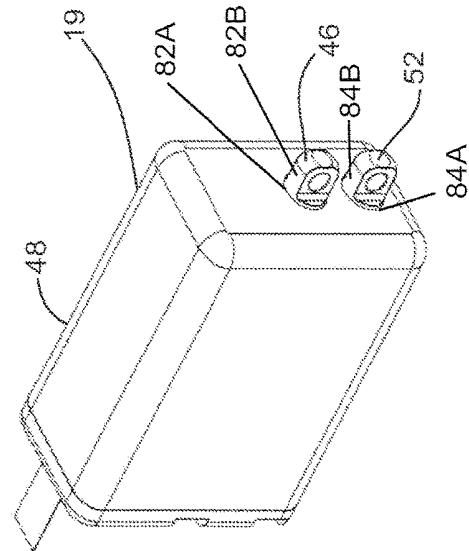


Fig. 2A

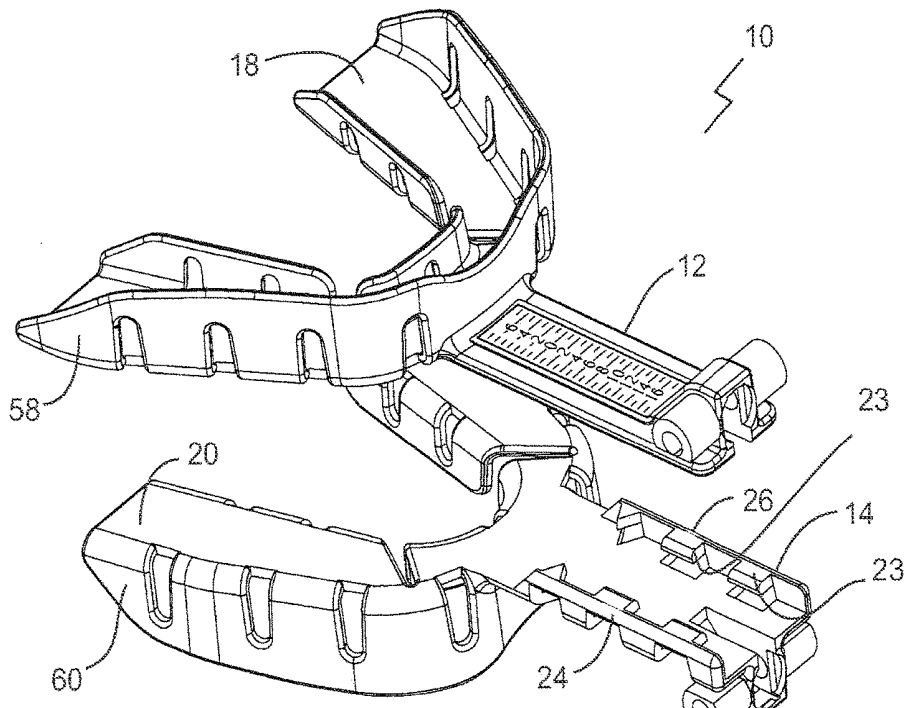


Fig. 3A

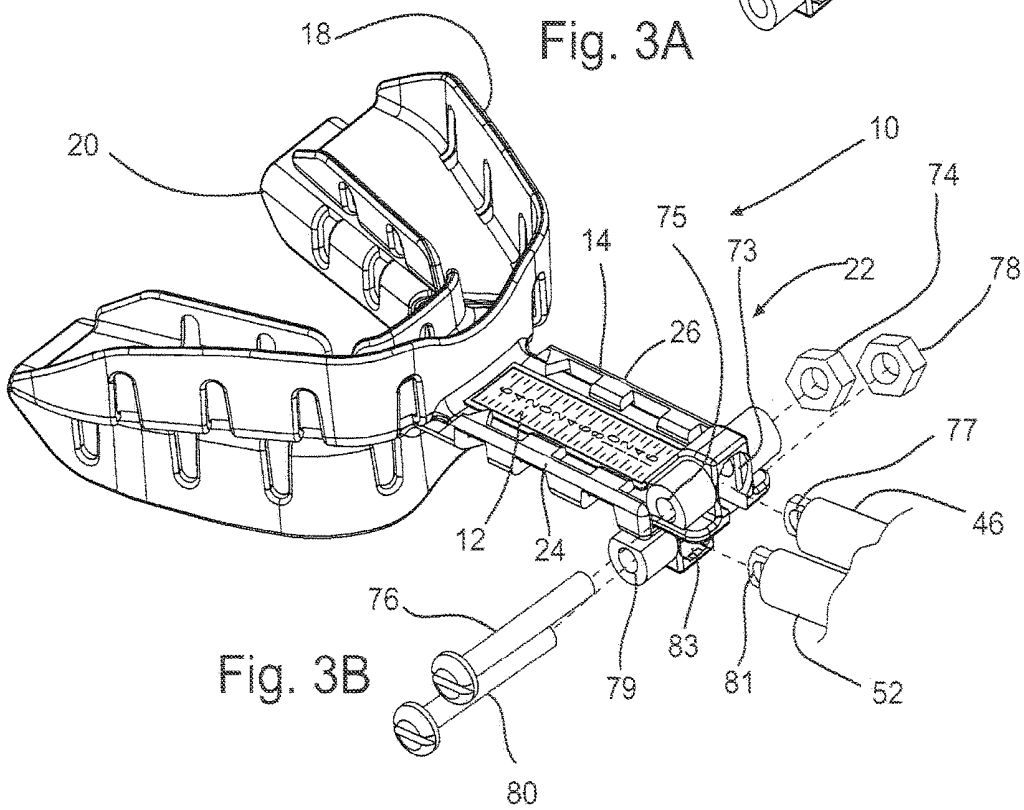


Fig. 3B

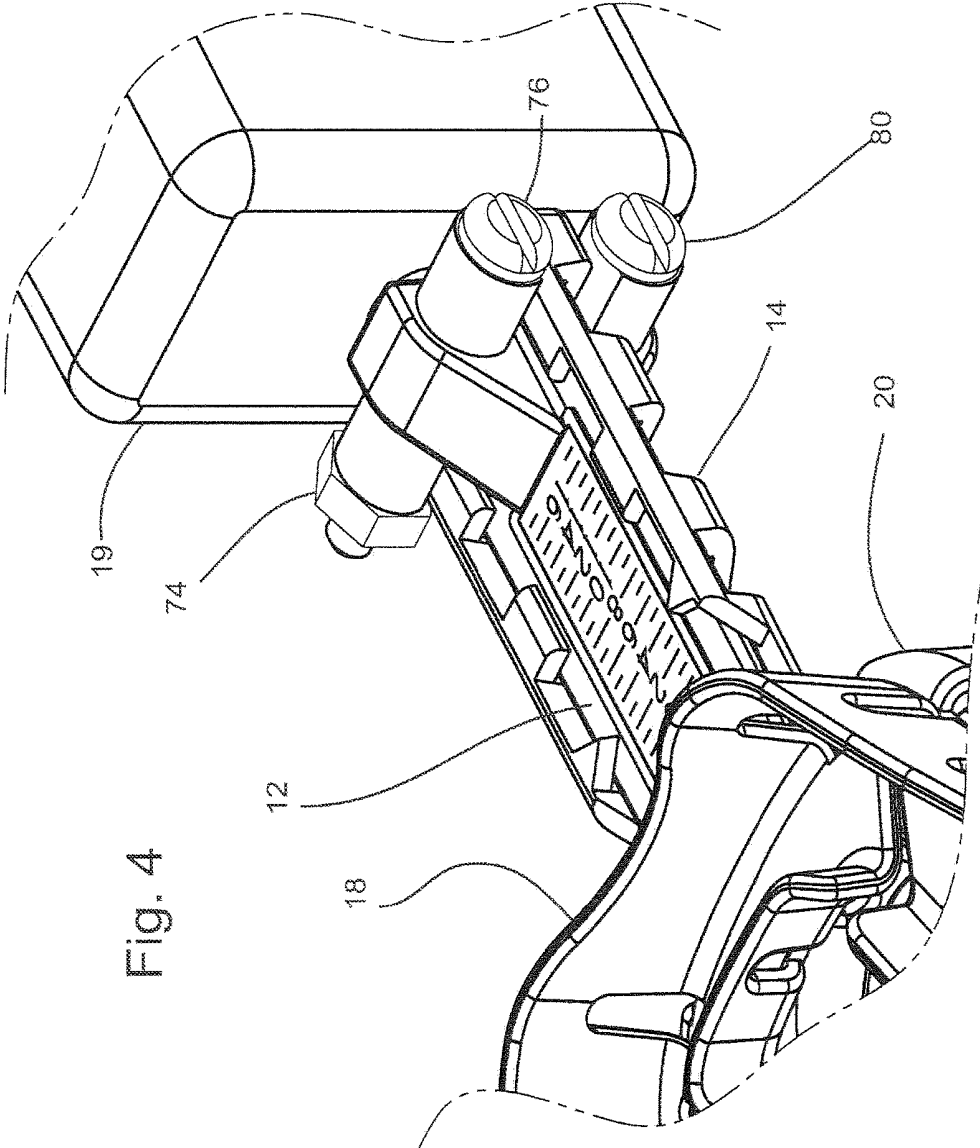
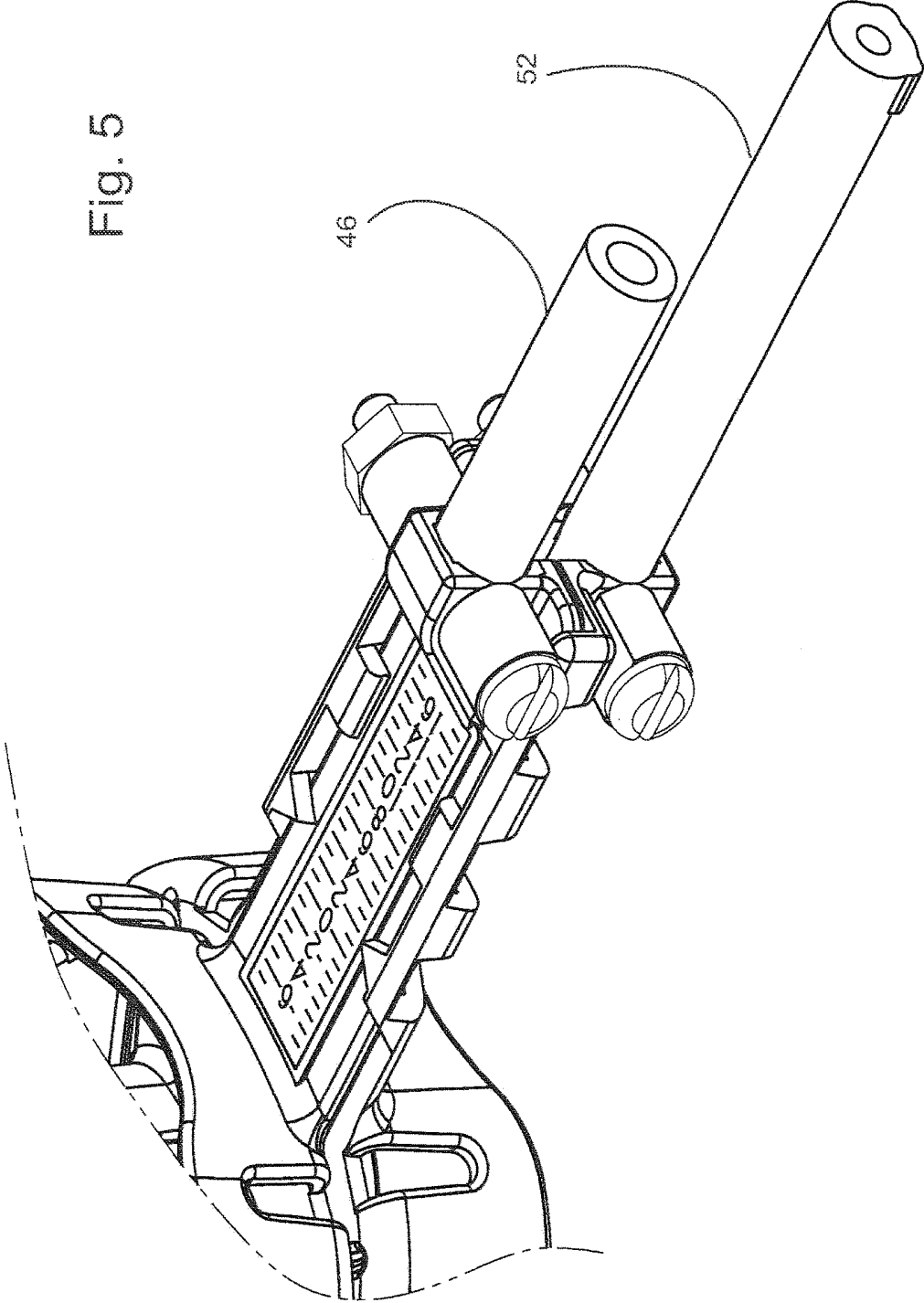


Fig. 4

Fig. 5



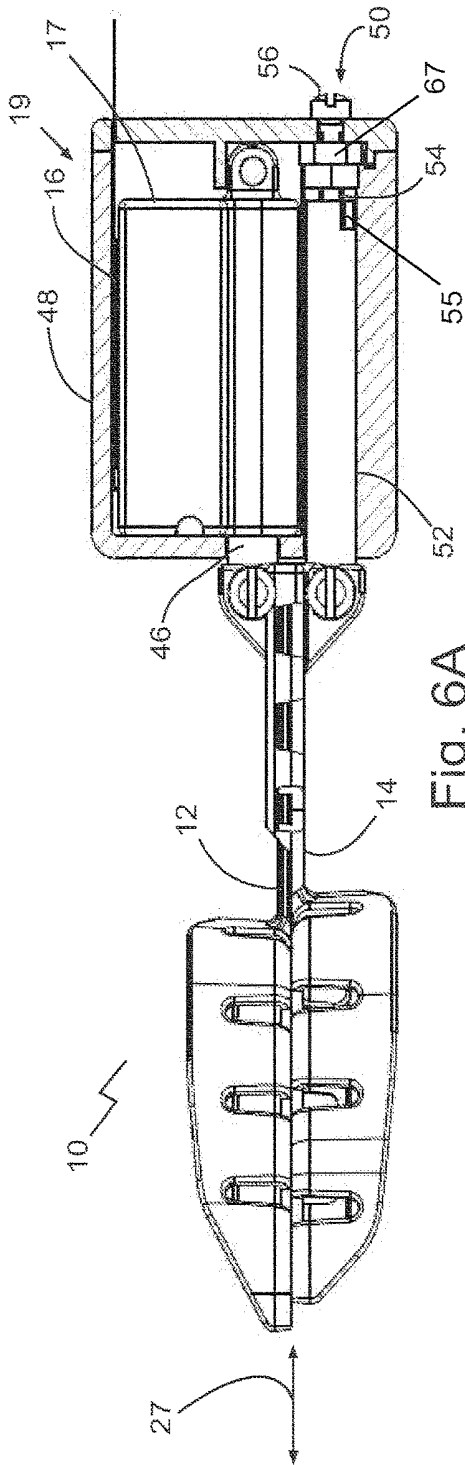


Fig. 6A

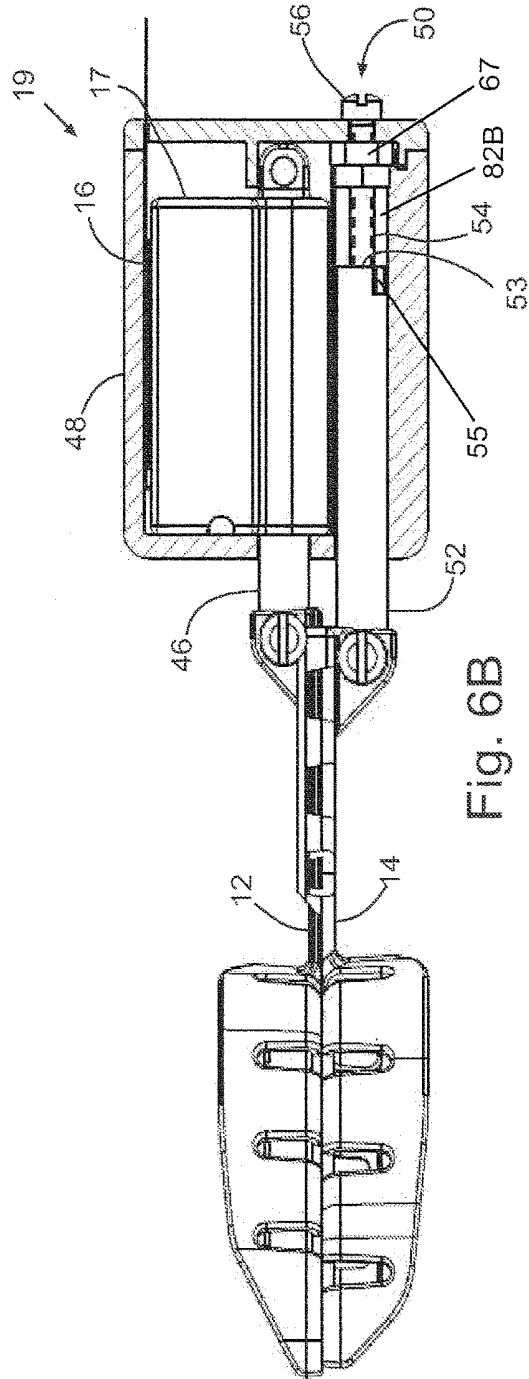


Fig. 6B

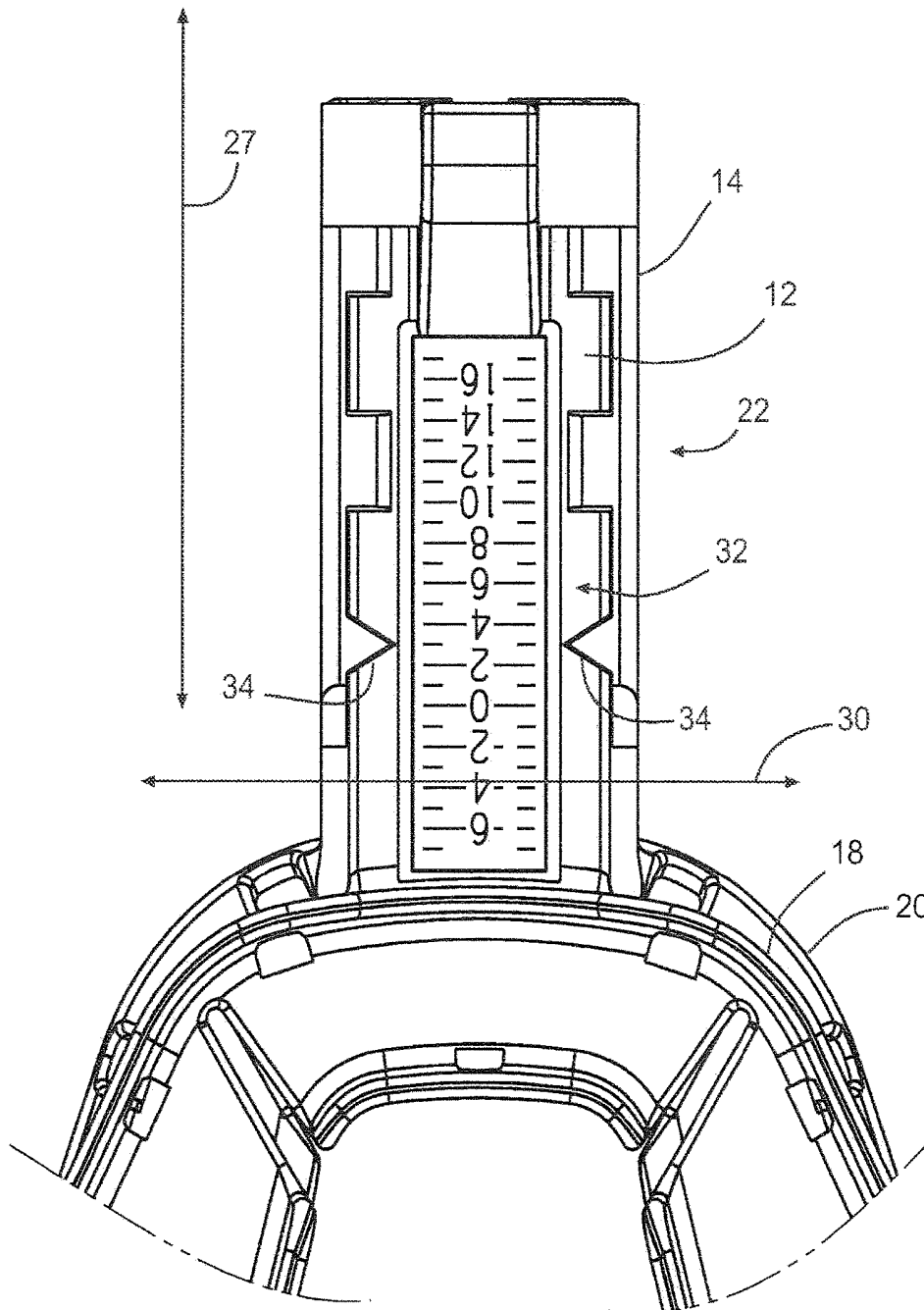


Fig. 7

Fig. 8

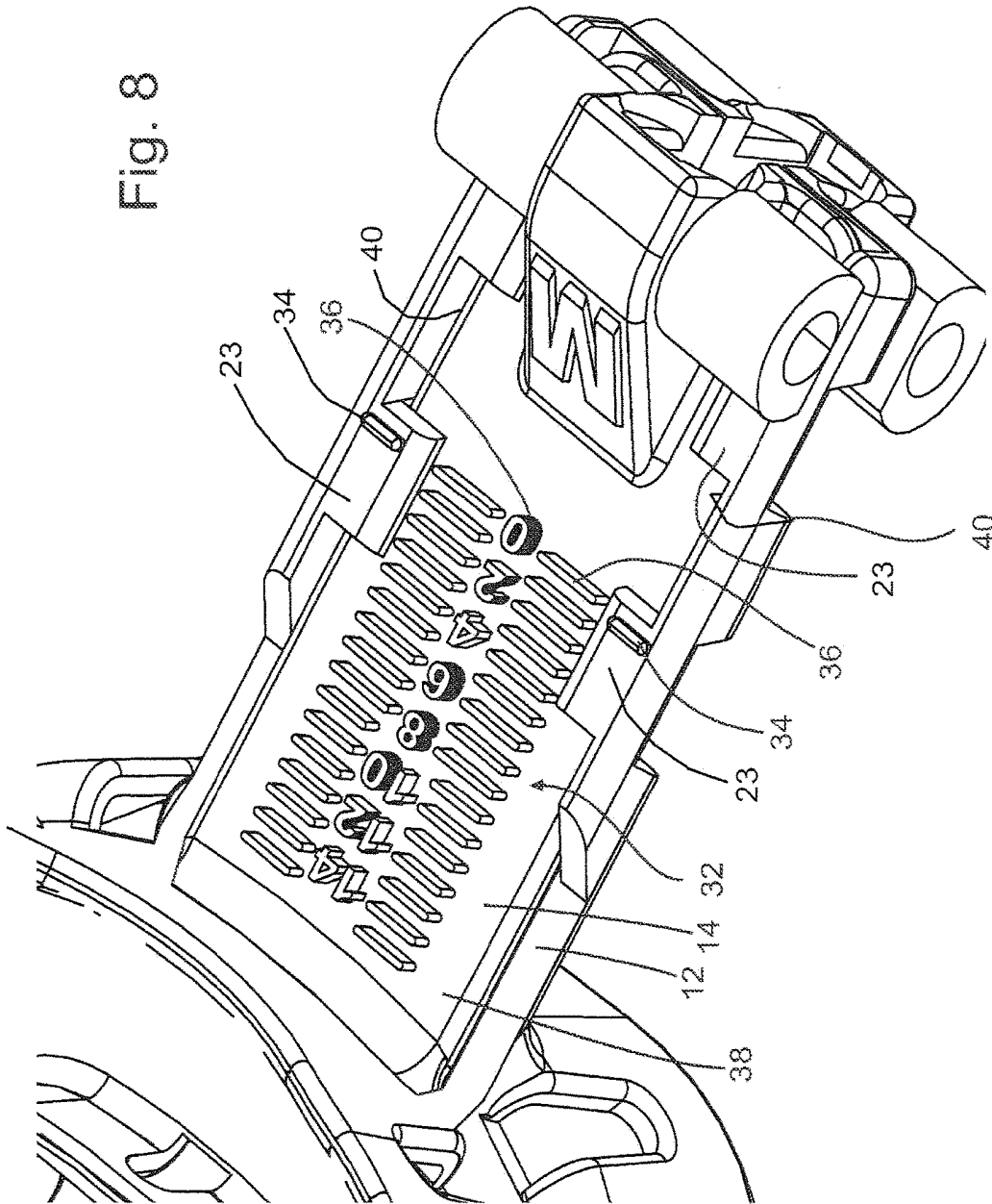
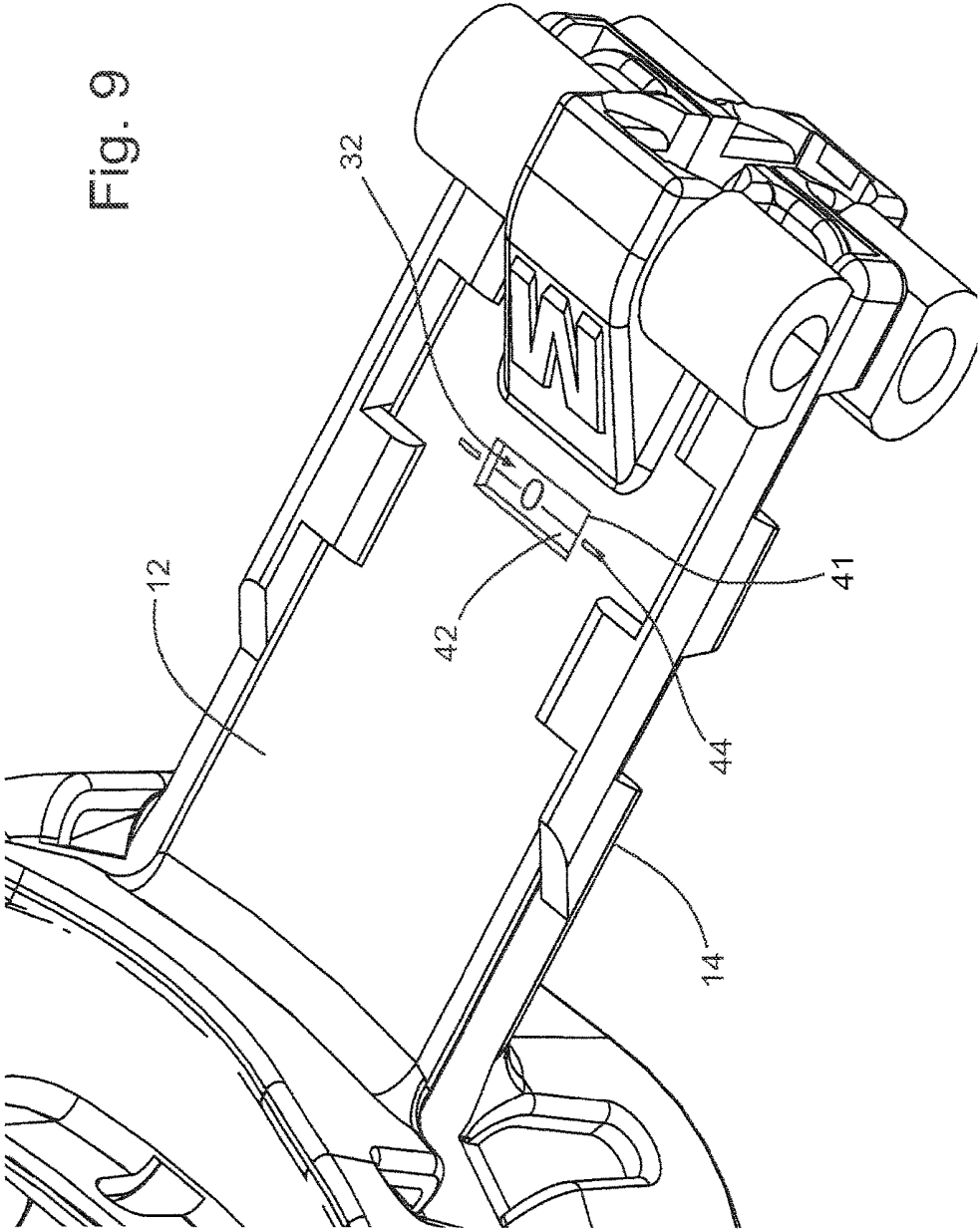


Fig. 9



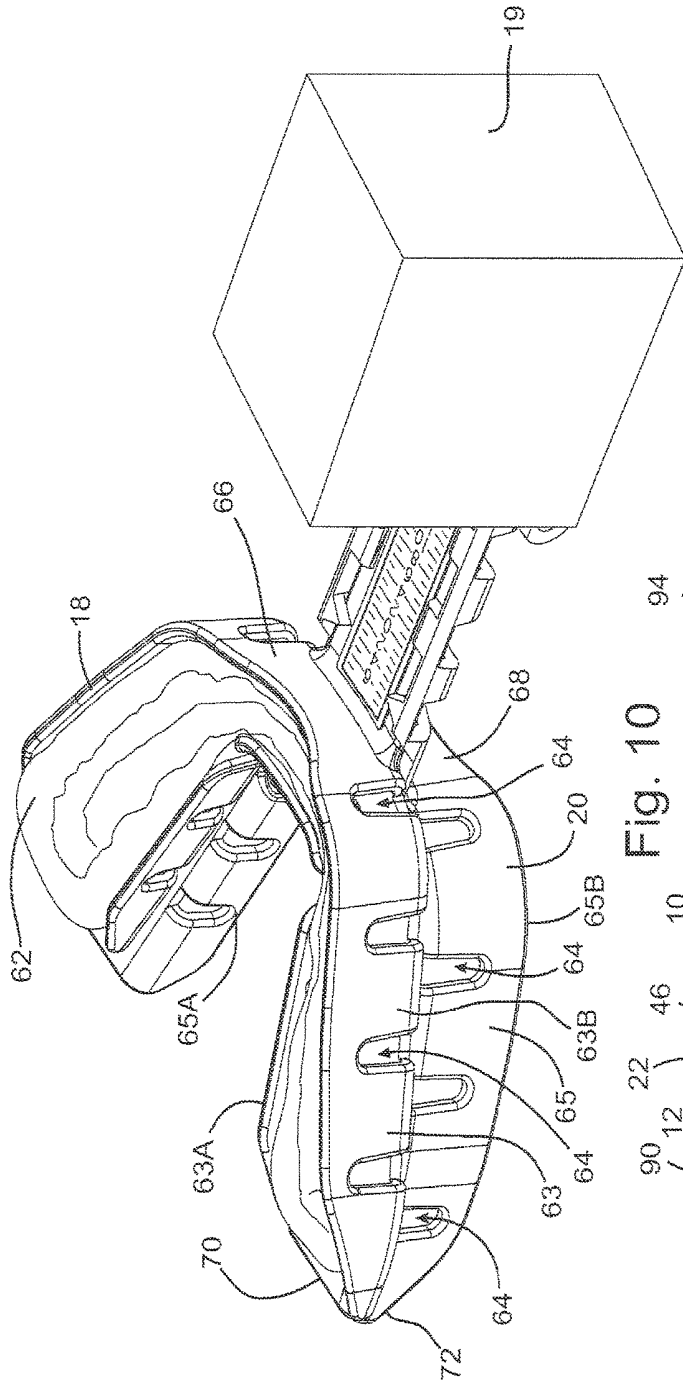


Fig. 10

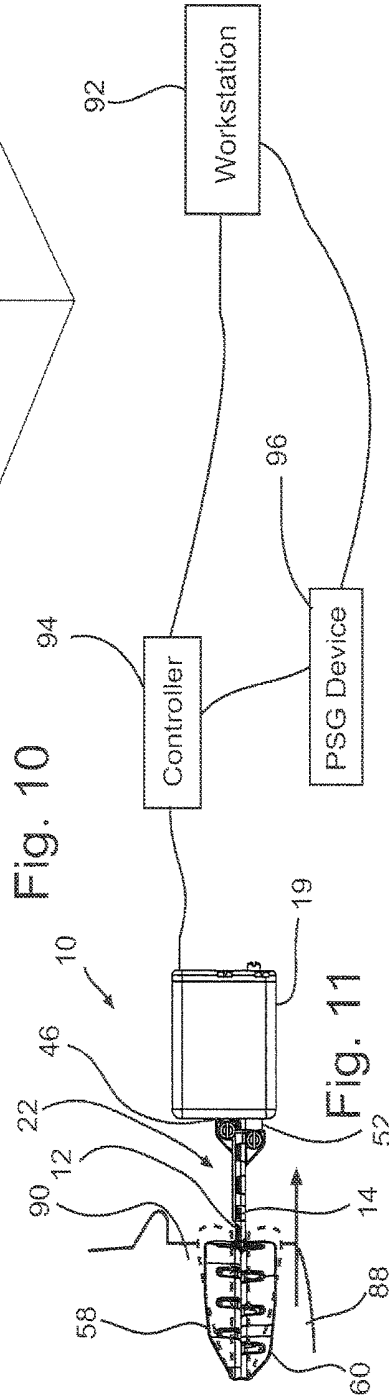
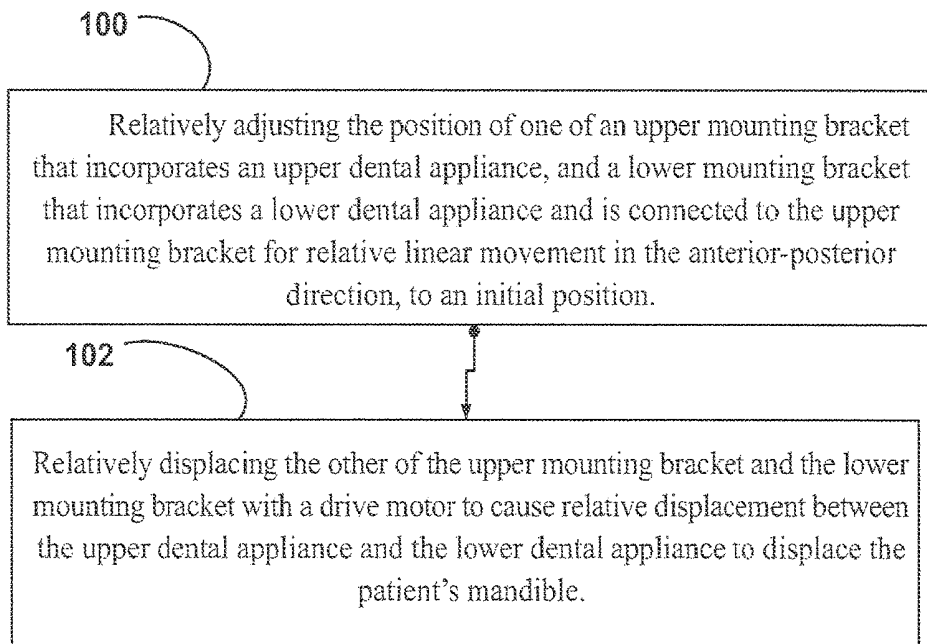


Fig. 11

**Fig. 12**

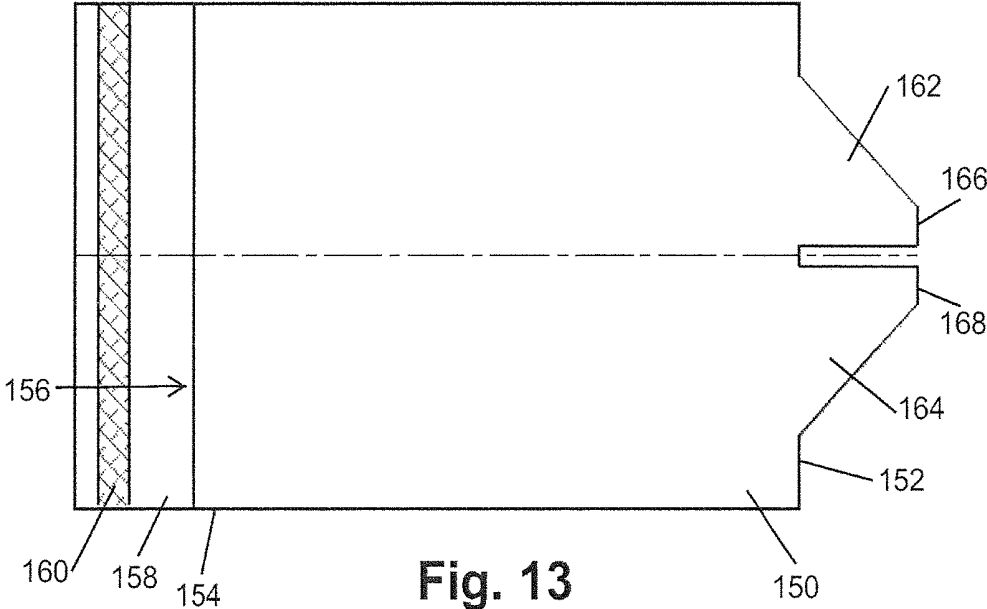


Fig. 13

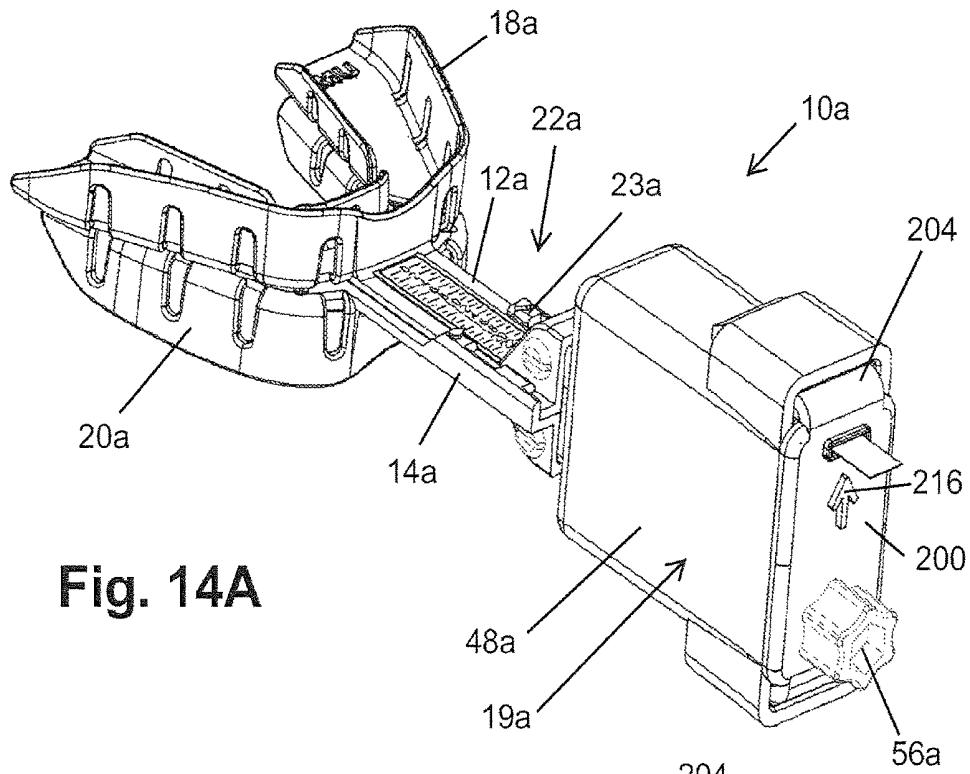


Fig. 14A

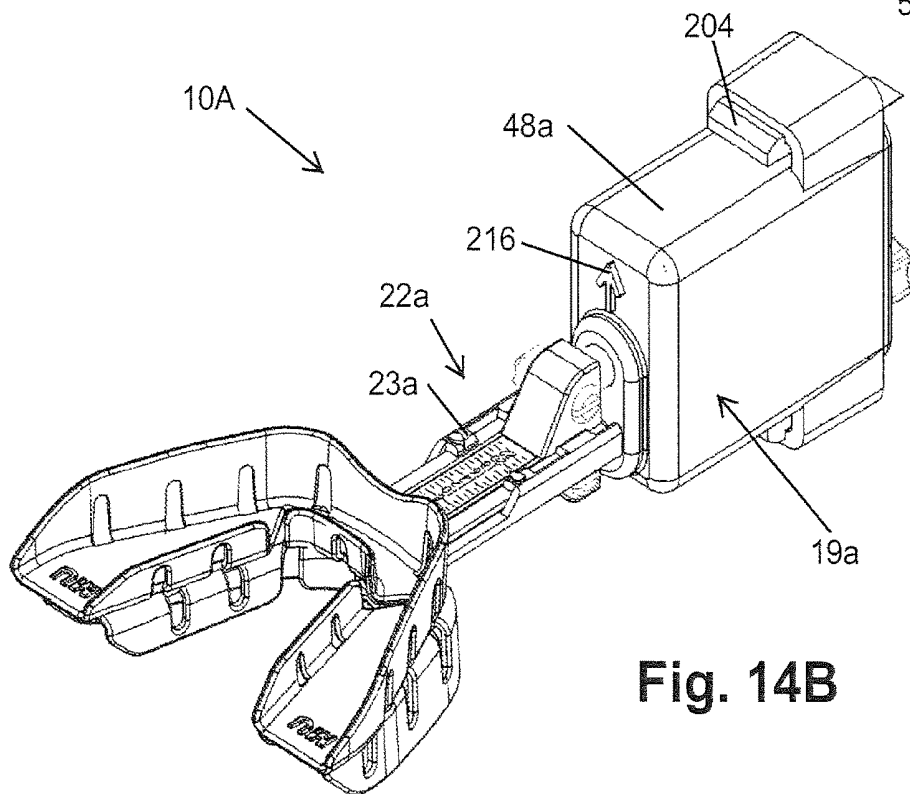


Fig. 14B

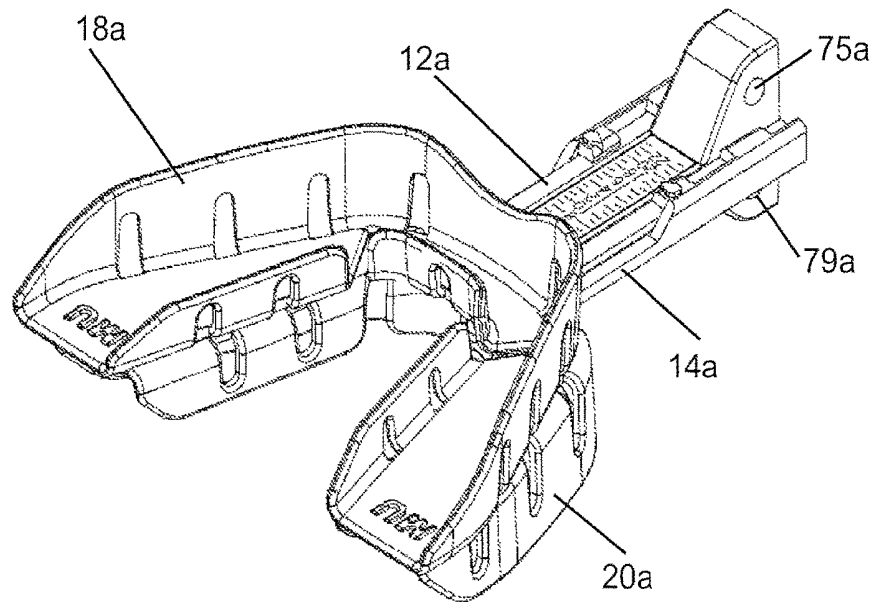


Fig. 14C

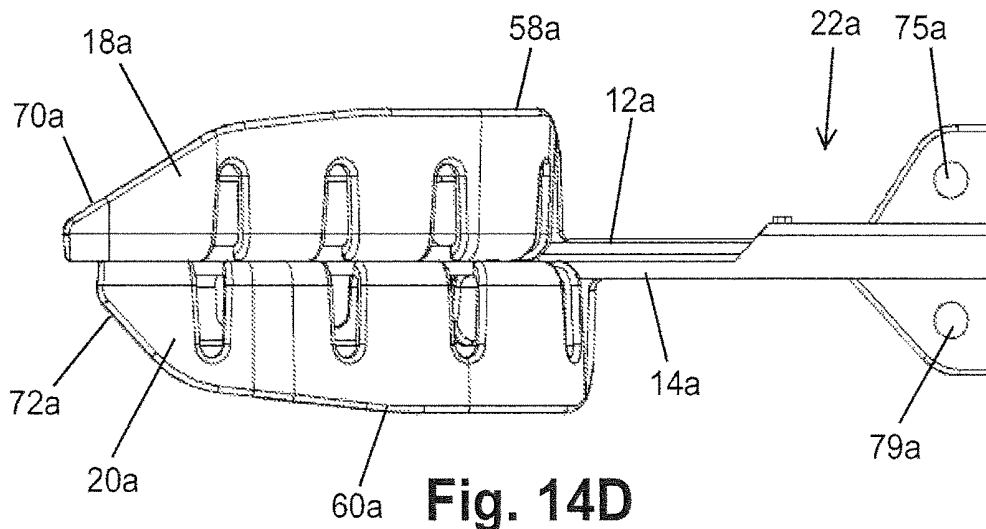


Fig. 14D

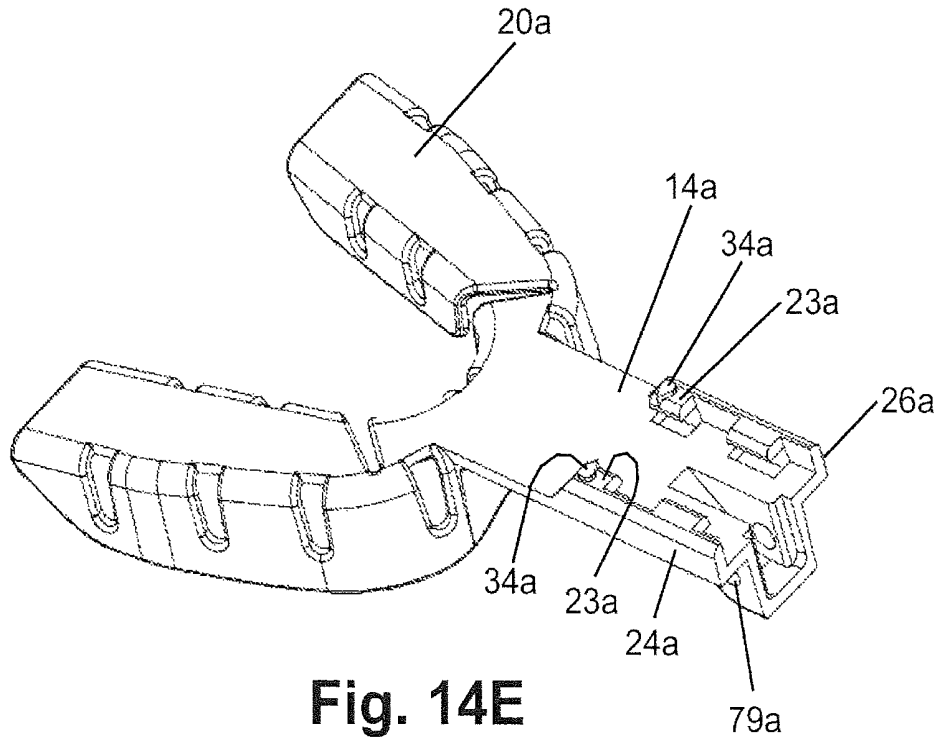


Fig. 14E

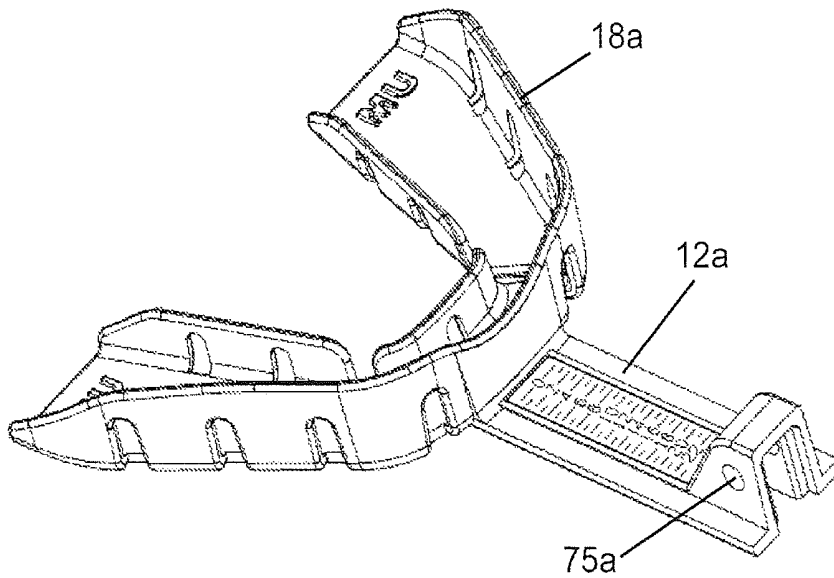


Fig. 14F

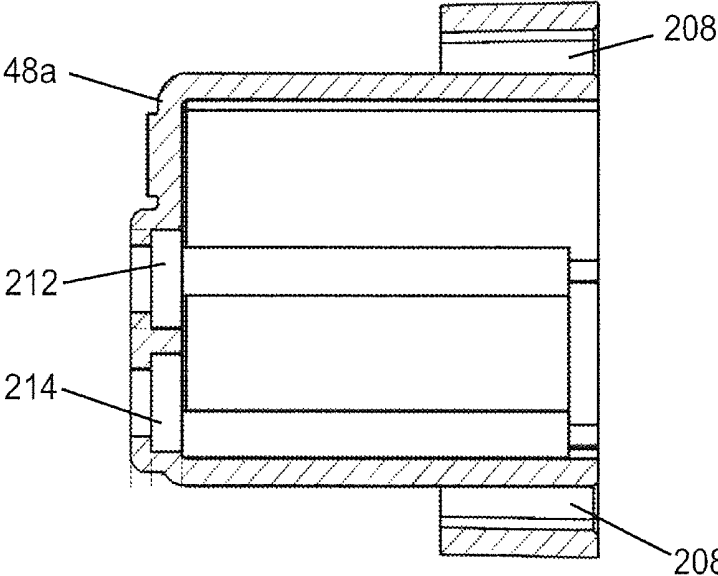


Fig. 14G

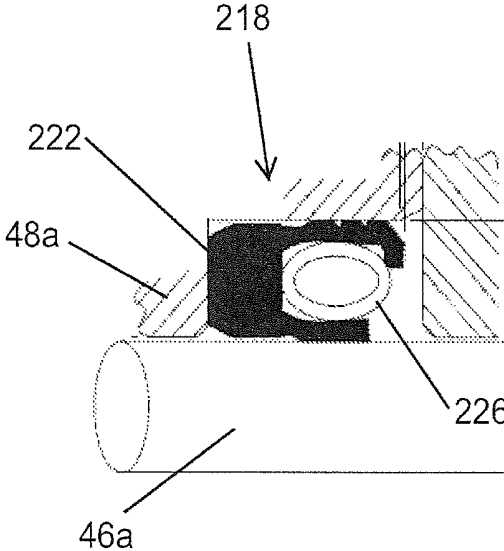


Fig. 14H

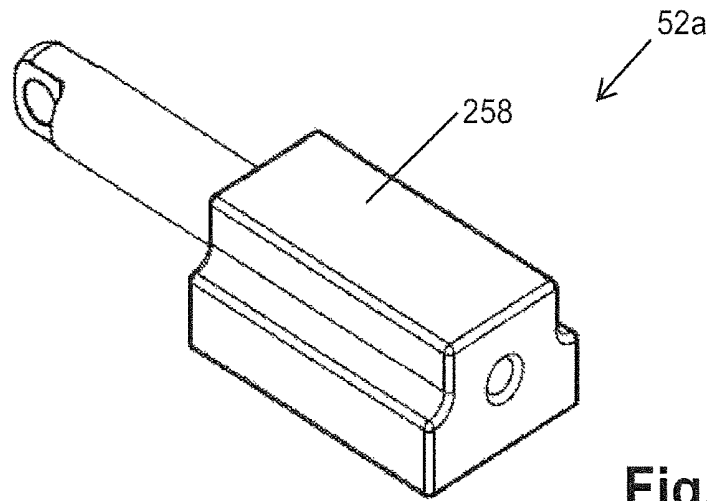


Fig. 15A

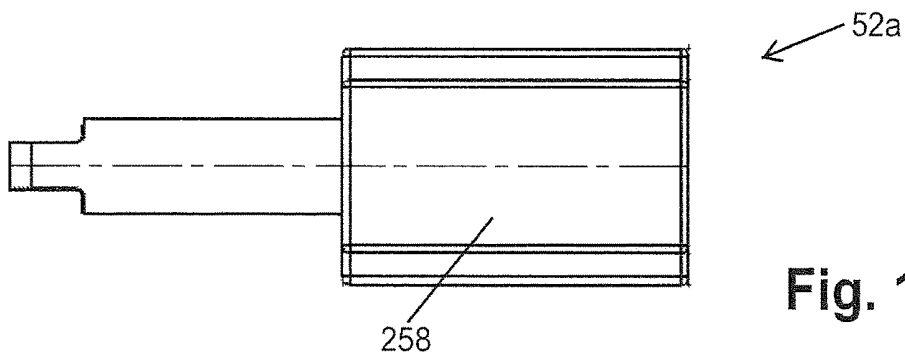


Fig. 15B

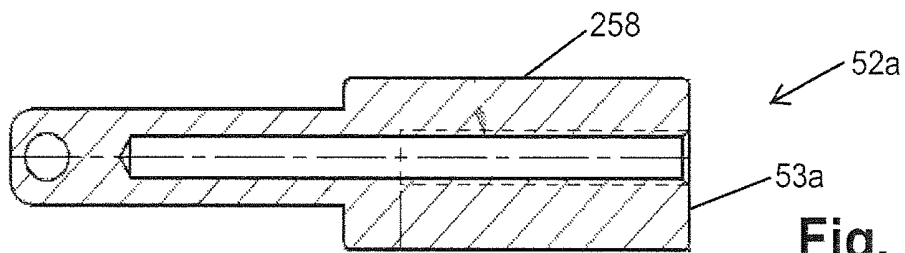


Fig. 15C

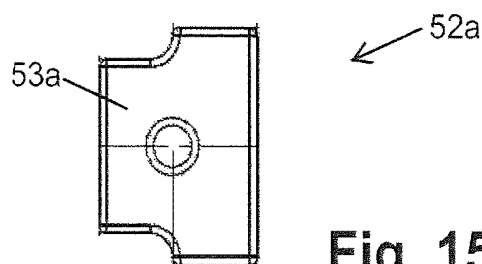


Fig. 15D

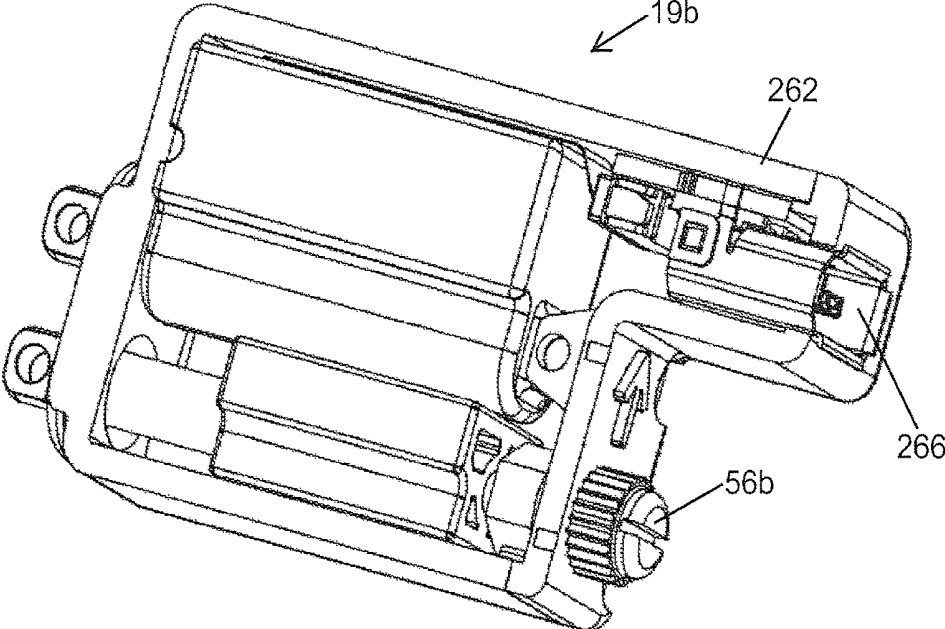


Fig. 16A

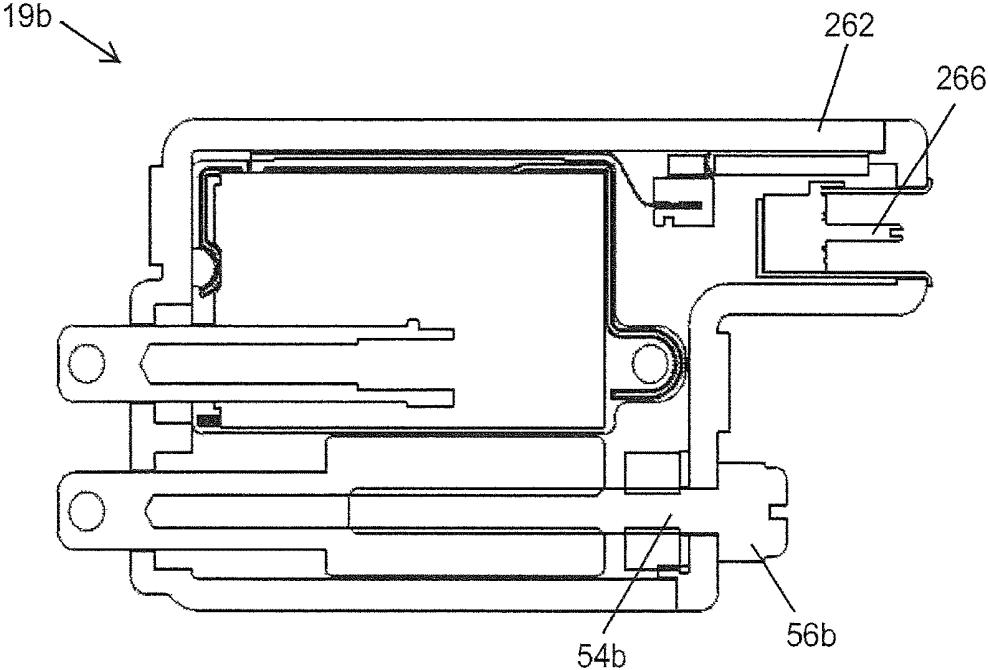


Fig. 16B

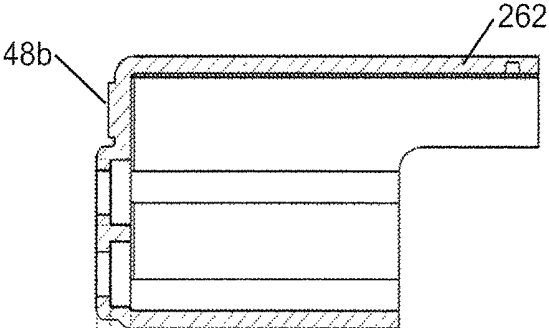


Fig. 16C

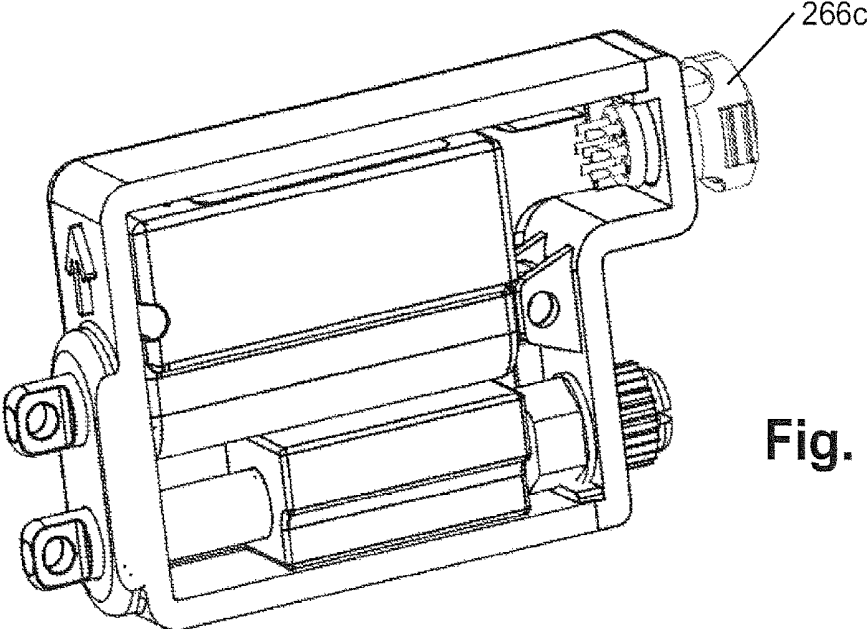


Fig. 17A

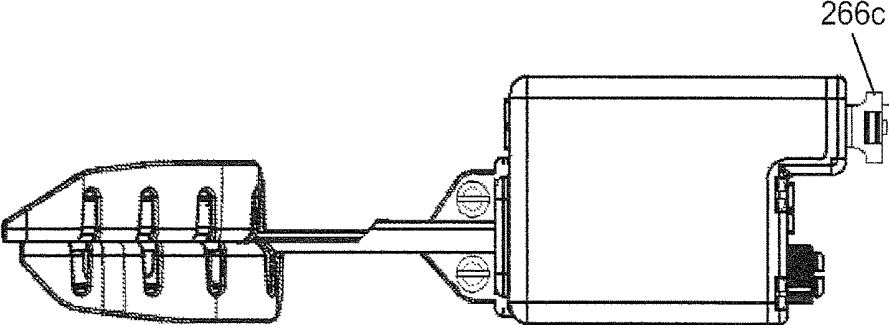


Fig. 17B

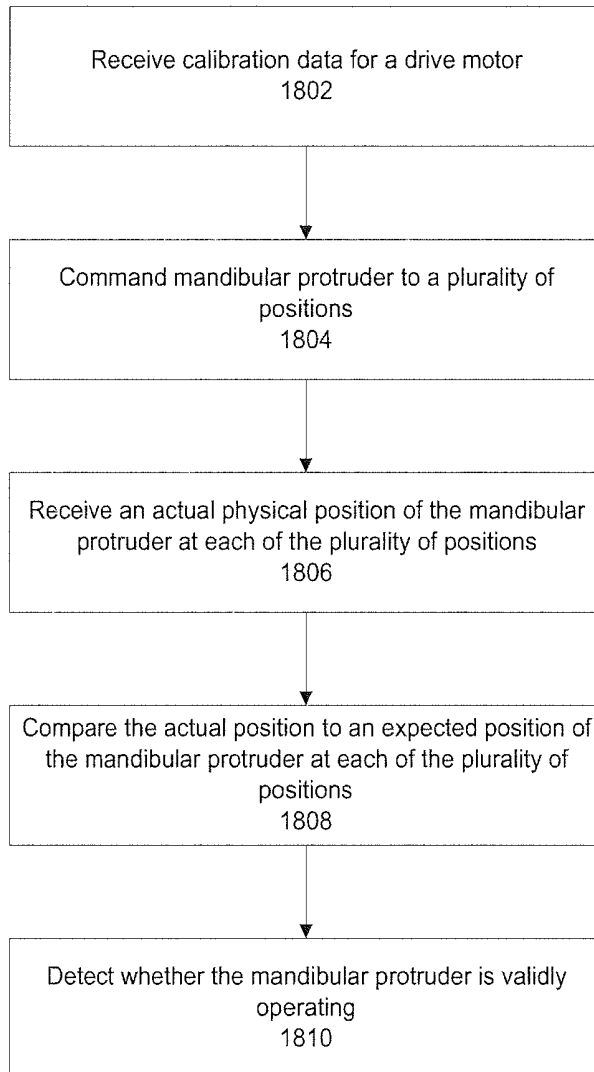


Fig. 18A

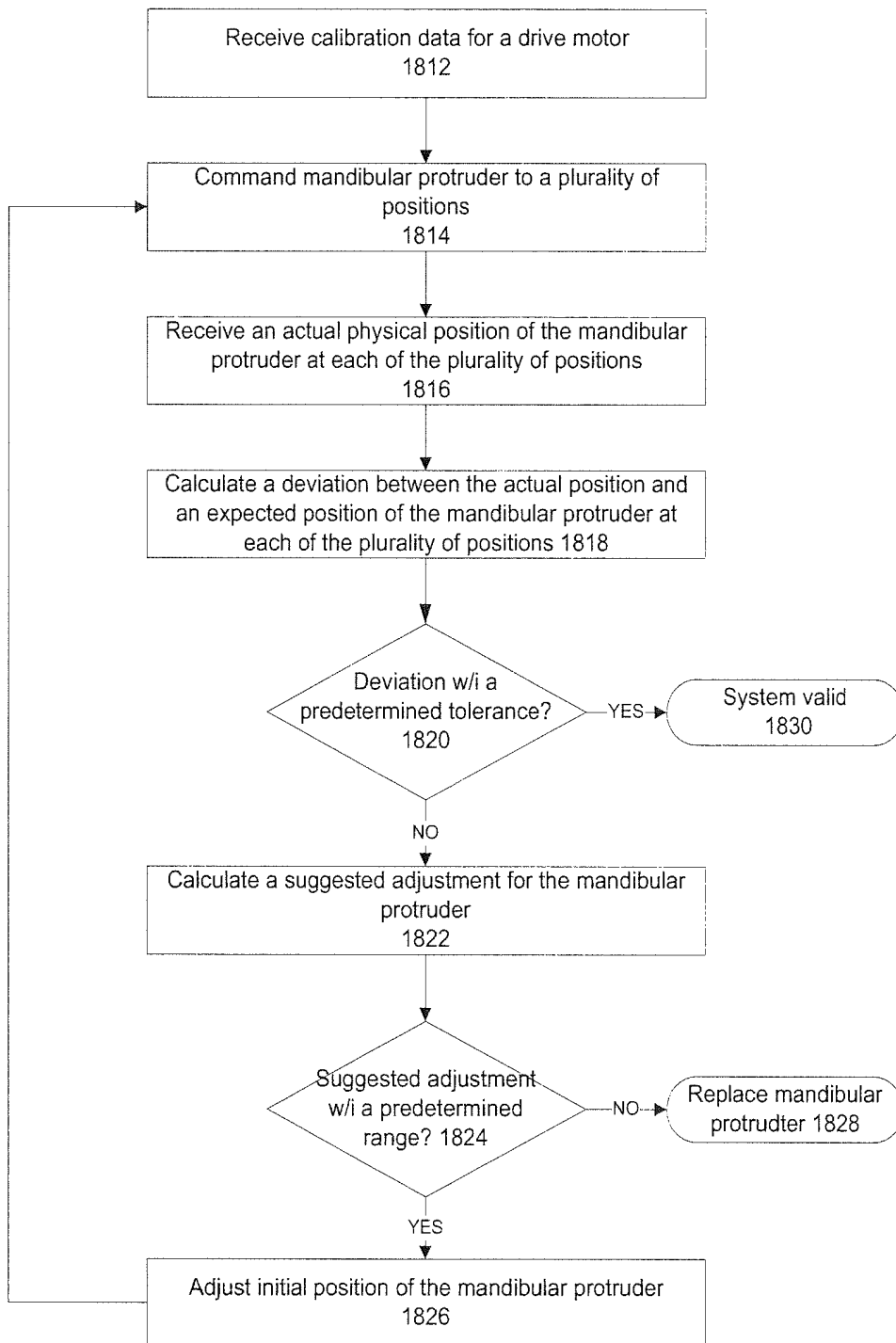
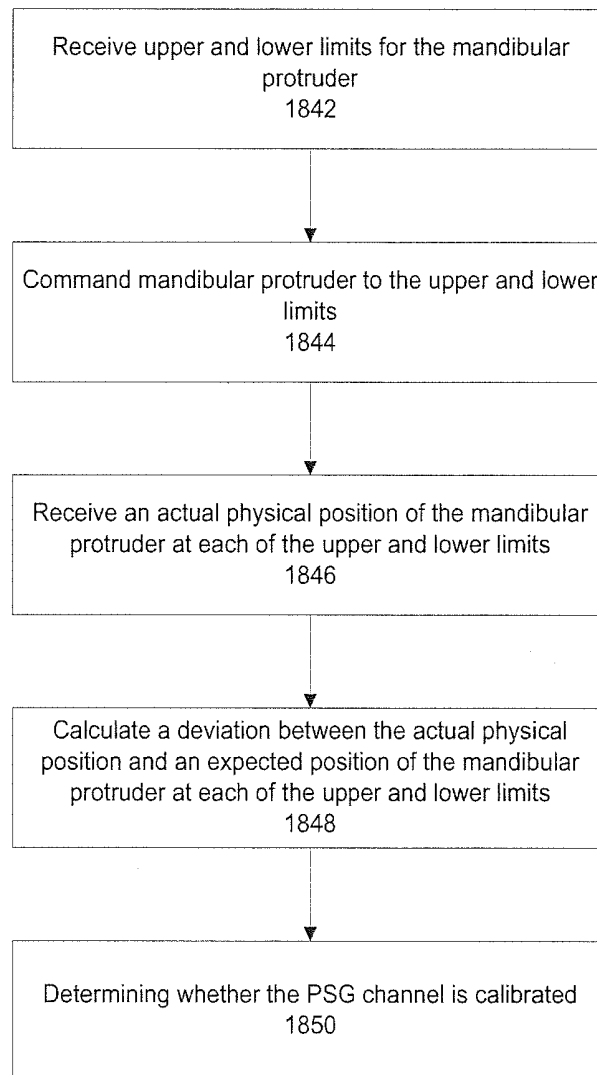
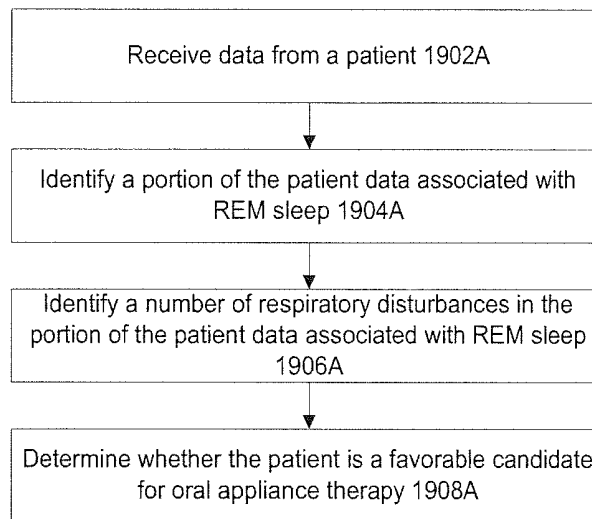
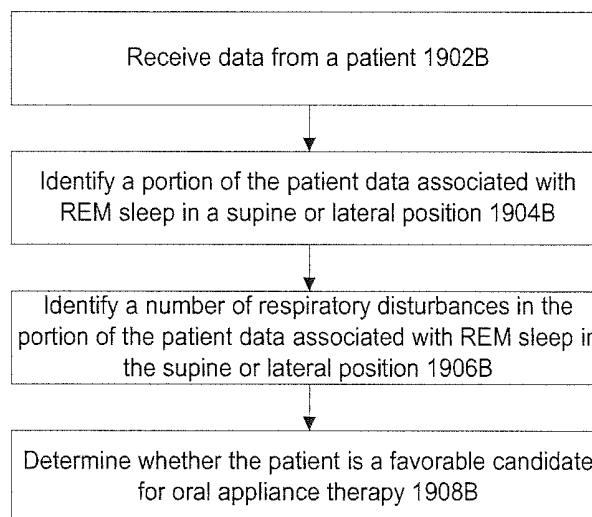


Fig. 18B

**Fig. 18C**

**Fig. 19A****Fig. 19B**

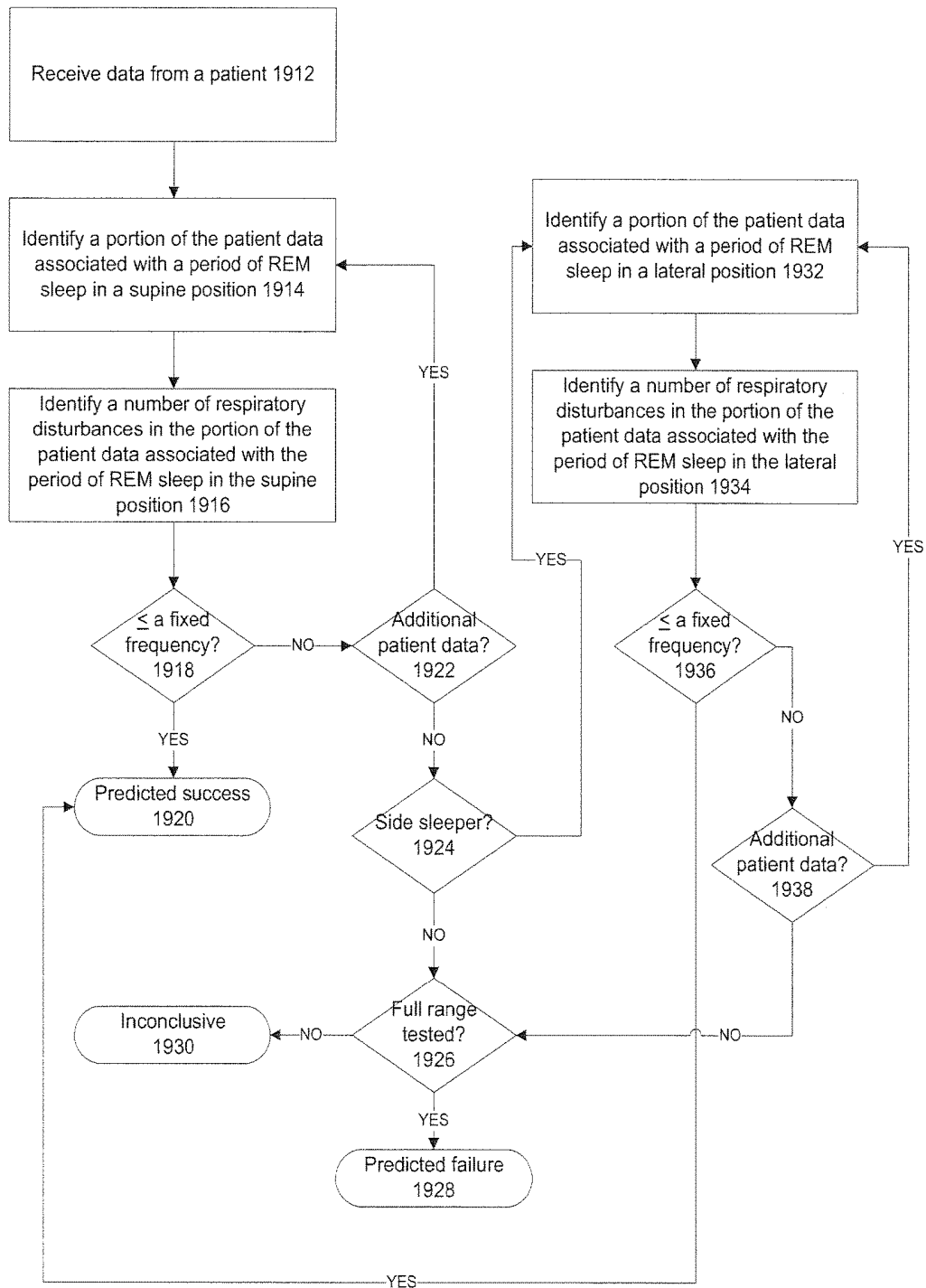


Fig. 19C

ORAL APPLIANCE THERAPY TITRATION CHART

TREATMENT LEVEL (mm)	TIB	TIME REM	TIME REM SUPINE	EVENTS SUPINE	TIME REM LATERAL	EVENTS LATERAL	OBS. APNEA	CEN. APNEA	MIXED APNEA	RESPIRATORY EVENTS					ALL RESP	RDI
										ALL HYPN'S	A+H TOTAL	AHI	RERA	ALL HYPN'S		
RCMP 9.9	0:28:12	0:00:00	0:00:00	6	0:00:00	0	0	0	0	6	6	28.7	0	6	28.7	
RCMP 10.4	0:42:03	0:00:00	0:00:00	6	0:00:00	2	0	0	0	8	8	27.5	0	8	27.5	
RCMP 10.3	0:12:54	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 10.5	0:09:06	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 10.7	0:06:37	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 10.8	0:05:32	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 11	0:03:38	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 11.2	0:02:55	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 11.5	0:03:23	0:00:00	0:00:00	3	0:00:00	0	0	0	0	3	3	53.3	0	3	53.3	
RCMP 11.7	0:09:43	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 11.9	0:11:24	0:00:00	0:00:00	1	0:00:00	0	0	0	0	1	1	5.3	0	1	5.3	
RCMP 12.1	0:05:02	0:01:00	0:00:40	3	0:00:20	1	0	0	0	4	4	47.6	0	4	47.6	
RCMP 12.3	0:02:12	0:02:24	0:00:12	1	0:02:12	0	0	0	0	1	1	27.2	0	1	27.2	
RCMP 12.5	0:02:52	0:06:44	0:03:52	1	0:02:52	0	0	0	0	1	1	20.9	0	1	20.9	
RCMP 12.7	0:13:40	0:12:12	0:08:37	1	0:03:35	1	0	0	0	2	2	9.5	0	2	9.5	
RCMP 12.9	0:07:03	0:01:00	0:01:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 13.1	0:03:55	0:05:55	0:05:55	1	0:00:00	0	0	0	0	1	1	15.3	0	1	15.3	
RCMP 13.2	0:06:30	0:00:00	0:00:00	0	0:00:00	0	0	0	0	3	3	27.7	0	3	27.7	
RCMP 13.4	0:10:53	0:00:00	0:00:00	0	0:00:00	0	0	0	0	3	3	20.3	0	3	20.3	
RCMP 13.6	0:05:49	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	
RCMP 13.9	0:13:48	0:04:16	0:03:38	1	0:00:38	0	0	0	0	1	1	4.3	0	1	4.3	
RCMP 14.1	1:16:40	0:00:00	0:00:00	3	0:00:00	0	0	0	0	8	8	7.1	0	8	7.1	
RCMP 14.2	0:23:48	0:14:48	0:12:24	0	0:02:24	1	0	0	0	0	0	0	0	0	0	
RCMP 13.7	0:25:55	0:03:48	0:02:20	0	0:01:28	0	0	0	0	0	0	0	0	0	0	
RCMP 14.4	0:48:26	0:20:00	0:19:30	3	0:00:30	1	0	0	0	3	3	4	0	3	4	
RCMP 14.6	0:16:11	0:00:00	0:00:00	0	0:00:00	0	0	0	0	0	0	0	0	0	0	

2001

FIG. 20

2001

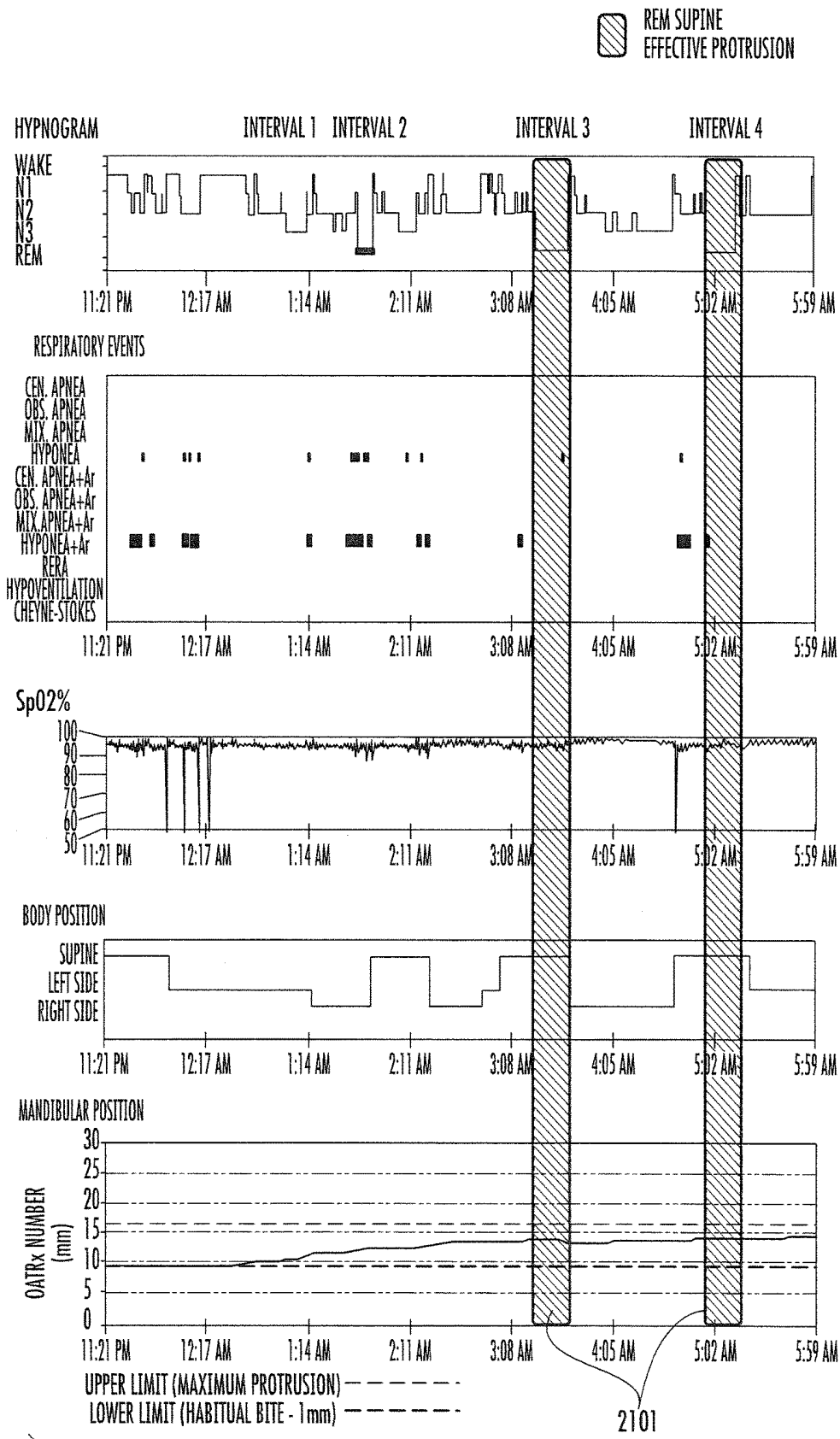


FIG. 21

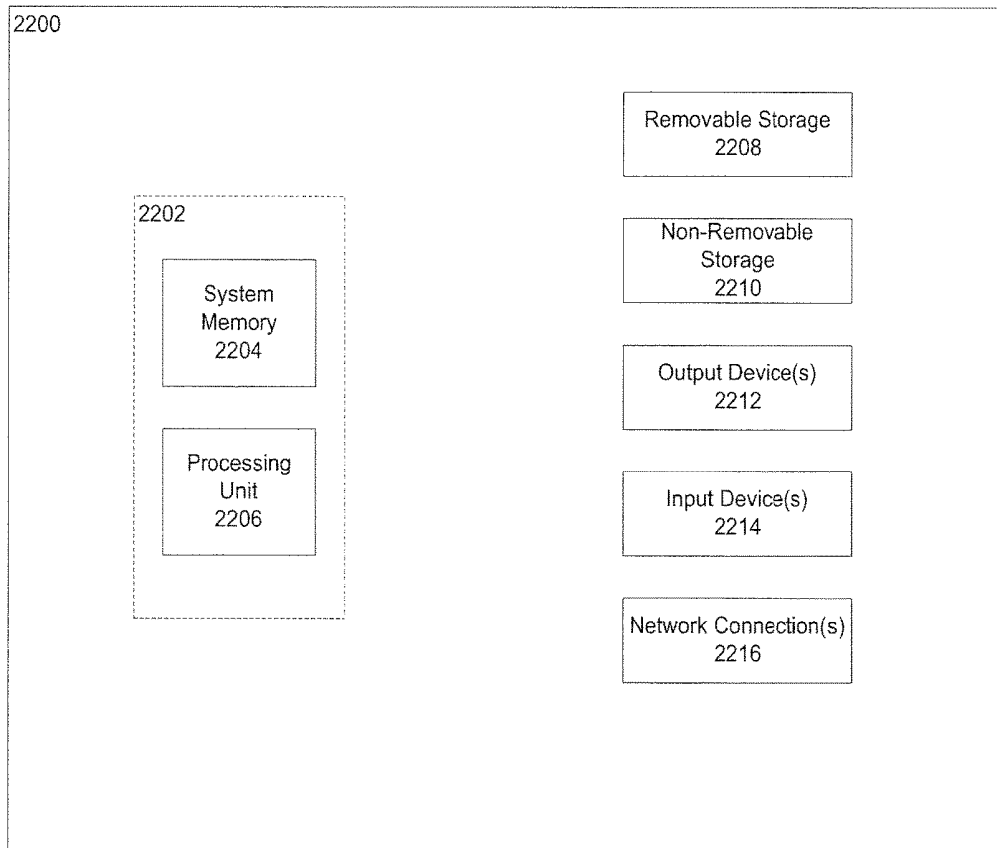


Fig. 22

**METHODS AND APPARATUSES FOR
PERFORMING REMOTE TITRATION OF
MANDIBULAR PROTRUSION**

CROSS-REFERENCE TO RELATED
APPLICATION

This application claims the benefit of U.S. Provisional Patent Application No. 61/659,231, filed on Jun. 13, 2012, entitled "Methods and Apparatuses for Performing Remote Titration of Mandibular Protrusion," the disclosure of which is expressly incorporated herein by reference in its entirety.

BACKGROUND

Obstructive sleep apnea (OSA) is a common disease that carries significant risks for cardiovascular disease, mortality, and economic costs. Almost thirty years ago, initial population studies found the prevalence of OSA to be five to nine percent of the adult population. Excess body weight is a risk factor for the development of OSA, and the recent rise in prevalence of obesity has led to revised estimates of OSA prevalence, now at seventeen percent of the adult population. OSA is poorly recognized clinically; currently 85% of apneics remain undiagnosed and untreated.

OSA derives fundamentally from structural abnormalities of the pharynx that cause pharyngeal narrowing or closure during sleep and produce recurrent apneas and hyponeas. During wakefulness, compensatory neuro-muscular reflexes protect the pharynx from collapse. These reflexes are lost during sleep, leaving the collapsible human pharynx susceptible to narrowing or closure. Nasal continuous positive airway pressure (CPAP), comprised of an air generator and nose mask, is the standard therapy for OSA. CPAP delivers positive pressure to the pharyngeal lumen, thereby dilating it and eliminating obstruction. While CPAP therapy is highly efficacious, it is cumbersome and its effectiveness is compromised by a relatively low adherence rate. Adherence depends on the methods used to initiate therapy and on the severity of OSA, being higher in subjects with more severe hypoxemia and excessive daytime sleepiness. In current practice, CPAP therapy adherence rate appears to approximate fifty percent.

The only currently available alternative to CPAP is oral appliance (OA) therapy. Oral appliances maintain patency of the airway during sleep by stabilizing and protruding the mandible and/or the tongue. The most commonly used type of OA is a custom-made mandibular repositioner (MR) which protrudes the mandible. Mandibular protrusion in paralyzed subjects dilates both the velopharynx and the oropharynx. In clinical practice, a specialist dentist fabricates a custom-fitted OA covering upper and lower teeth. The appliance is then empirically adjusted to progressively protrude the mandible until a therapeutic end-point is reached. MR therapy is better accepted by the OSA subject than nasal CPAP therapy, and self-reported adherence rates are high. Unfortunately, MR therapy is not uniformly effective in OSA. Reported effectiveness ranges from 50 to 65 percent, and a recent study found 50 percent success rate.

Because of the uncertainties regarding use of MR therapy for treating OSA, current practices focus primarily on the use of nasal CPAP therapy. Virtually all subjects found to have OSA receive a trial of nasal CPAP. If the subjects prove non-adherent with CPAP therapy, the subjects may then be offered MR therapy. The American Academy of Sleep Medicine recommends MR therapy as a CPAP therapy alternative in subjects with OSA of mild to moderate sever-

ity. However, lacking a valid test for clinically selecting subjects with OSA who will have a favorable response to MR therapy, reimbursement for MR therapy is usually provided only for apneics who fail CPAP therapy.

SUMMARY

Methods and apparatus for performing system validation and providing predictive criteria during remote titration of mandibular protrusion are disclosed herein. The effectiveness of MR therapy can possibly be improved by screening OSA subjects to prospectively identify those suitable for MR therapy and providing a target therapeutic protrusive distance. Development of a set of criteria that can be consistently applied and that require the minimum amount of data can possibly increase the effectiveness and efficiencies of the test. Moreover, even if a subject were known to be a favorable candidate, the dentist currently has no way to determine the target therapeutic protrusive position. Studies of the passive pharynx indicate that the response of the pharynx to mandibular protrusion is 'dose dependent.' For example, incremental mandibular protrusion produces corresponding pharyngeal enlargement. However, clinical experience shows that excessive mandibular protrusion is undesirable, producing side effects, such as, pain and tooth movement that lead to discontinuation of therapy. Current practice is for the dentist to progressively protrude the mandible until a symptomatic response occurs, and then reassess the subject to determine if OSA has resolved. Thus, prospective identification of suitable candidates and target protrusive positions would facilitate treatment of OSA with MR therapy. Additionally, in contrast to titration systems that are manually adjusted (i.e., where the scale can be read directly from the titration device), an unattended titration (i.e., remote titration systems) requires that a control system is accurately reading the physical position of the device. Thus, methods for validating operation of the titration system are disclosed herein.

A device that can be used to identify favorable candidates for MR therapy and predict the therapeutic protrusive distances is disclosed herein. The device, called a remotely controlled mandibular protruder (RCMP), includes upper and lower dental trays which are inserted into the mouth and connected to a small extra-oral motor which moves the mandibular tray relative to the maxillary tray and, thereby, protrudes the mandible. This device is also discussed in detail in U.S. Patent Application Pub. No. 2010/0316973, titled "APPARATUSES AND METHODS FOR MANDIBULAR PROTRUSION," to Remmers et al., filed Jun. 4, 2010, which is incorporated herein in its entirety by reference. The device is applied during polysomnography, where sleep and cardio-respiratory variables are continuously recorded while the subject sleeps overnight in a sleep laboratory, and the position is controlled remotely by a sleep technologist in an adjacent room. The protrusive distance applied to the teeth are displayed on the polysomnographic monitor and the technologist moves the mandible, step-wise, while monitoring the changes in cardio-respiratory variables. The goal of the test is to determine: (1) whether or not mandibular protrusion reduces evidence of pharyngeal obstruction, and (2) the minimum protrusive distance required to eliminate obstruction.

An example method for identifying a candidate for oral appliance therapy can include: receiving data from a patient while the patient was sleeping with a dental appliance; identifying at least a portion of the data associated with a period of REM sleep; identifying a number of respiratory

disturbances in the portion of the data associated with the period of REM sleep; and determining whether the patient is a favorable candidate for oral appliance therapy based on the number of respiratory disturbances in the portion of the data associated with the period of REM sleep. The patient data can be associated with one or more periods of rapid eye movement (REM) sleep and non-REM sleep. Optionally, the method can prioritize the use of data collected during REM sleep stages over data collected during one or more non-REM sleep stages, for example, by using only patient data collected during REM sleep stages. The patient data can be collected from a polysomnography equipment, portable sleep recorders (either Level II or III) or another method of collecting physiologic data while the patient is sleeping.

Optionally, a frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep can be less than or equal to a fixed frequency. For example, the fixed frequency can be 1 respiratory disturbance per 5 minute period. Additionally, the patient can be considered a favorable candidate for oral appliance therapy when the frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep is less than or equal to the fixed frequency.

In some implementations, the period of REM sleep can be equal to or greater than 5 minutes. In addition, the period of REM sleep can include a continuous, uninterrupted period of REM sleep. Alternatively, the period of REM sleep can include a plurality of fragmented periods of REM sleep.

In another implementation, the data can also be associated with one or more periods of sleep in a supine position and a lateral position. The method can further include: identifying a portion of data associated with a period of REM sleep in the supine position; identifying a number of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position; and determining whether the patient is a favorable candidate for oral appliance therapy based on the number of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position.

Similarly to above, a frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position can be less than or equal to a fixed frequency. For example, the fixed frequency can be 1 respiratory disturbance per 5 minute period. Additionally, the patient can be considered a favorable candidate for oral appliance therapy when the frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position is less than or equal to the fixed frequency.

In some implementations, the period of REM sleep in the supine position can be equal to or greater than 5 minutes. In addition, the period of REM sleep in the supine position can include a continuous, uninterrupted period of REM sleep. Alternatively, the period of REM sleep in the supine position can include a plurality of fragmented periods of REM sleep.

In another implementation, the period of REM sleep in the supine position can be less than 5 minutes. In this implementation, the method can further include: identifying a portion of data associated with a period of REM sleep in the lateral position; identifying a number of respiratory disturbances in the portion of the data associated with the period of REM sleep in the lateral position; and determining whether the patient is a favorable candidate for oral appliance therapy based on the number of respiratory disturbances in the portion of the data associated with the period of REM sleep in the lateral position.

Similarly to above, a frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep in the lateral position can be less than or equal to a fixed frequency. For example, the fixed frequency can be 1 respiratory disturbance per 5 minute period. Additionally, the patient can be considered a favorable candidate for oral appliance therapy when the frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep in the lateral position is less than or equal to the fixed frequency.

In some implementations, the period of REM sleep in the lateral position can be equal to or greater than 5 minutes. In addition, the period of REM sleep in the lateral position can include a continuous, uninterrupted period of REM sleep. Alternatively, the period of REM sleep in the lateral position can include a plurality of fragmented periods of REM sleep.

In yet another implementation, the period of REM sleep in the lateral position can be less than 5 minutes. In this case, the method can further include determining that the data is inconclusive.

In some implementations, the dental appliance can be a remote-control mandibular protruder, and the data can be collected during an oral appliance titration study of the patient while the patient was sleeping with the remote-control mandibular protruder.

Optionally, the period of REM sleep in the supine position (or alternatively the lateral position) can be greater than or equal to 5 minutes and a frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position (or alternatively the lateral position) can be greater than a fixed frequency. In this implementation, the method can further include: identifying whether the data includes data collected for a predetermined titration range; and in the event that the data includes data collected during the predetermined titration range, determining that the patient is not a favorable candidate for oral appliance therapy. Optionally, the predetermined range can include a maximum protrusion of the remote-control mandibular protruder or other titration appliance. Optionally, the maximum protrusion can be approximately the maximum protrusion of the remote-controlled mandibular protruder, for example, within 1 mm of the maximum protrusion or within a certain percentage of the maximum protrusion (e.g., 10% of the protrusive range). Alternatively, the predetermined range can include the range provided by a dentist, the maximum voluntary protrusion of the patient, or some other maximum protrusion range.

Alternatively or additionally, the method can further include, in the event that the data does not include data collected during the predetermined titration range, determining that the data is inconclusive.

In another implementation, a method for identifying a patient having mild to moderate sleep apnea as a candidate for oral appliance therapy can include: receiving data from a patient while the patient was sleeping with a dental appliance; identifying at least a portion of the data associated with a period of REM sleep in the supine position or the lateral position; identifying a number of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position or the lateral position; and determining whether the patient is a favorable candidate for oral appliance therapy based on the number of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position or the lateral position. Additionally, the data can be associated with one or more periods of rapid eye movement (REM) sleep and non-REM sleep and one or more periods of sleep in a supine

position or a lateral position. Optionally, a patient with mild to moderate sleep apnea has a respiratory disturbance index (RDI) less than 30.

Similarly to above, a frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position or the lateral position can be less than or equal to a fixed frequency. For example, the fixed frequency can be 1 respiratory disturbance per 5 minute period. Additionally, the patient can be considered a favorable candidate for oral appliance therapy when the frequency of respiratory disturbances in the portion of the data associated with the period of REM sleep in the supine position or the lateral position is less than or equal to the fixed frequency.

In some implementations, the period of REM sleep in the supine position or the lateral position can be equal to or greater than 5 minutes. In addition, the period of REM sleep in the supine position or the lateral position can include a continuous, uninterrupted period of REM sleep. Alternatively, the period of REM sleep in the supine position or the lateral position can include a plurality of fragmented periods of REM sleep.

In yet another implementation, the method can further include determining an effective protrusion distance. For example, the effective protrusion distance can be a minimum protrusion distance corresponding to a portion of data associated with a period of REM sleep in the supine position and/or the lateral position, where the frequency of respiratory disturbances in the portion of the data is less than or equal to the fixed frequency.

A method for displaying results of a titration study of an obstructive sleep apnea therapy of a patient according to an implementation can include: receiving data associated with the titration study; and displaying the data for a plurality of steps of the titration study such that an amount of mandibular protrusion is displayed in relation to at least one of a sleep stage, a count of respiratory events, a sleep position and an oximetry level at each step of the titration study. The data can include at least two of sleep stages, counts of respiratory events, sleep positions, oximetry levels and amounts of mandibular protrusion.

Optionally, the sleep stages can include rapid eye movement (REM) and one or more stages of non-REM sleep. In this implementation, the method can further include displaying only portions of the data associated with the REM sleep for a plurality of steps of the titration study such that an amount of mandibular protrusion is displayed in relation to at least one of a sleep stage, a count of respiratory events, a frequency of respiratory events in REM, a sleep position and an oximetry level at each step of the titration study.

Additionally, the method can optionally include displaying a chart, where a plurality of rows or columns are arranged by time at each step of the titration study, and an amount of mandibular protrusion is displayed in a same row or column as at least one of a sleep stage, a count of respiratory events, a sleep position and an oximetry level at each step of the titration study.

Alternatively, the method can optionally include displaying a graphical hypnogram, where amounts of mandibular protrusion are displayed in temporal relation to at least one of sleep stages, counts of respiratory events, sleep positions and oximetry levels for each step of the titration study.

Optionally, the method can further include highlighting a portion of the chart or the hypnogram including data associated with REM sleep. For example, the portion of the chart or the hypnogram can include a segment of REM sleep

exceeding a predetermined period of time and a corresponding count of respiratory events.

A method for validating operation of an oral appliance titration system including a mandibular protruder having a drive motor can include: receiving calibration data for the drive motor; commanding the mandibular protruder to a plurality of positions; receiving an actual physical position of the mandibular protruder at each of the plurality of commanded positions; comparing the actual position to an expected position of the mandibular protruder at each of the plurality of commanded positions; and detecting whether the titration system is validly operating based on the comparison.

In some implementations, the calibration data can define a response of the drive motor within a predetermined tolerance. For example, the response of the drive motor can be linear. Additionally, the calibration data can be an n-character string defining the linear response of the drive motor.

Optionally, the method can include comparing the actual physical position to an expected position of the mandibular protruder by calculating a deviation between the actual physical position and a detected feedback position of the mandibular protruder for each of the plurality of commanded positions. The detected feedback position can be related to the calibration data. Additionally, the method can include determining whether the titration system is operating validly based on the calculated deviation for each of the plurality of commanded positions.

In some implementations, the titration system is validly operating when the deviation at each of the plurality of commanded positions is within the predetermined tolerance. For example, the predetermined tolerance can be ± 0.5 mm.

Optionally, the actual physical position of the mandibular protruder can be determined using a scale on the mandibular protruder. Additionally, the detected feedback position can be related to a detected voltage and the calibration data.

In other implementations, the method can include commanding the mandibular protruder to the plurality of commanded positions by commanding the mandibular protruder to at least three positions. For example, the at least three positions can be a fully retruded position of the mandibular protruder, a fully protruded position of the mandibular protruder and a position between the fully retruded and fully protruded positions.

In another implementation, the deviation at one or more of the plurality of commanded positions is not within the predetermined tolerance. In this implementation, the method can include: calculating a suggested adjustment for the mandibular protruder; determining whether the suggested adjustment is within a predetermined range; and in response to determining that the suggested adjustment is within the predetermined range, adjusting an initial position of the mandibular protruder based on the suggested adjustment.

Optionally, the suggested adjustment can be an average of the deviations for the plurality of commanded positions. Additionally, the predetermined range can be within ± 2.0 mm.

In yet another implementation, the method can include: re-commanding the mandibular protruder to the plurality of commanded positions; receiving an updated actual physical position of the mandibular protruder at each of the plurality of commanded positions; calculating an updated deviation between the updated actual physical position and an updated detected feedback position of the mandibular protruder for each of the plurality of commanded positions; and determining whether the titration system is validly operating

based on the calculated updated deviation for each of the plurality of commanded positions.

Additionally, the titration system is validly operating when the updated deviation at each of the plurality of commanded positions is within the predetermined tolerance.

In some implementations, the method can include, in response to determining that the suggested adjustment is not within the predetermined range, recommending replacing the mandibular protruder.

In some implementations, the deviation at one or more of the plurality of commanded positions is not within the predetermined tolerance. In this case, the method can further include: calculating a suggested adjustment for the mandibular protruder; calculating a difference between the deviation at each of the plurality of commanded positions and the suggested adjustment; determining whether the difference is within a drive motor tolerance range; and in response to determining that the difference is not within the drive motor tolerance range, recommending replacing the drive motor.

In yet another implementation, the titration system also includes a polysomnogram or other sleep data collection system. Additionally, the method can further include calibrating a channel of the polysomnogram. The method for calibrating the channel of the polysomnogram can include: receiving an upper limit and a lower limit for the mandibular protruder; commanding the mandibular protruder to the upper limit and the lower limit; receiving an actual physical position of the mandibular protruder at each of the upper limit and the lower limit; calculating a deviation between the actual physical position and a detected feedback position of the mandibular protruder for each of the upper limit and the lower limit; and determining whether the channel of the polysomnogram is calibrated based on the calculated deviation for each of the upper limit and the lower limit.

Optionally, the channel of the polysomnogram is calibrated when the deviation at each of the upper limit and the lower limit is within the predetermined tolerance. For example, the predetermined tolerance can be ± 0.5 mm. Additionally, the upper limit and the lower limit can be patient-specific limits. In particular, the upper limit and the lower limit can be related to a fully protruded and a fully retracted position of a patient's jaw.

Alternatively or additionally, the method can also include: determining whether the actual physical position of the mandibular protruder is greater than the upper limit or less than the lower limit; and upon determining that the actual physical position of the mandibular protruder is greater than the upper limit or less than the lower limit, providing a warning.

It should be understood that the above-described subject matter may also be implemented as a computer-controlled apparatus, a computer process, a computing system, or an article of manufacture, such as a computer-readable storage medium.

Other systems, methods, features and/or advantages will be or may become apparent to one with skill in the art upon examination of the following drawings and detailed description. It is intended that all such additional systems, methods, features and/or advantages be included within this description and be protected by the accompanying claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The components in the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding parts throughout the several views.

FIGS. 1A-1C are side elevation views of one of the present mandibular protruders. In FIG. 1A, upper and lower dental trays of the protruder are in a fully retracted position, in FIG. 1B the upper dental tray is extended and the lower dental tray is in the fully retracted position, and in FIG. 1C the upper dental tray is retracted and the lower dental tray is at least partially extended from the retracted position of FIG. 1A.

FIG. 2 is a side elevation view of the mandibular protruder of FIG. 1A with the dental trays retracted to the zero point on the scale.

FIG. 2A is a perspective view of a mandibular positioning device suitable for use in the mandibular protruder of FIG. 1A.

FIGS. 3A and 3B are perspective views of the upper and lower dental trays suitable for use in the mandibular protruder of FIG. 1A.

FIG. 4 is a perspective view of the rail system of the mandibular protruder of FIG. 1A.

FIG. 5 is a further perspective view of the rail system of a mandibular protruder of FIG. 1A shown without a portion of the mandibular positioning device.

FIGS. 6A and 6B are partially cutaway, side elevation views of the mandibular protruder of FIG. 1A showing the lower dental tray in fully retracted and offset positions, respectively.

FIG. 7 is a top plan view of a relative position indicator of the mandibular protruder of FIG. 1A, that includes a displacement scale.

FIG. 8 is a perspective view of another embodiment of a relative position indicator that incorporates a ribbed displacement scale, and that is suitable for use in embodiments of the present mandibular protruders.

FIG. 9 is a perspective view of another embodiment of a relative position indicator that incorporates a reference window for a displacement scale, and that is suitable for use in embodiments of the present mandibular protruders.

FIG. 10 is a perspective view of one of the present mandibular protruders shown with bite material, shaped to fit a user's teeth, fitted in the upper and lower dental trays.

FIG. 11 is a schematic illustrating an exemplary system for carrying out a sleep titration on a patient with a mandibular protruder.

FIG. 12 is a flow diagram of one of the present methods of displacing a patient's mandible relative to the patient's maxilla.

FIG. 13 depicts an embodiment of the present polymeric bags suitable for use with some embodiments of the present devices.

FIGS. 14A-14B are perspective views of another embodiment of the present mandibular protruders.

FIGS. 14C-14D are enlarged perspective and side views, respectively, of an upper mounting bracket and lower mounting bracket of the protruder of FIGS. 14A-14B.

FIG. 14E is a top perspective view of the lower mounting bracket of the protruder of FIGS. 14A-14B.

FIG. 14F is a top perspective view of the upper mounting bracket of the protruder of FIGS. 14A-14B.

FIG. 14G is a cross-section of a housing of the protruder of FIGS. 14A-14B.

FIG. 14H is a cross-sectional view of a seal suitable for use in some embodiments of the present mandibular protruders.

FIGS. 15A-15D are various views of an adjustment-mechanism connector or rod suitable for use in embodiments of the present protruders.

FIGS. 16A-16B are cutaway-perspective and side cross-sectional views, respectively, of another embodiment of the present positioning devices.

FIG. 16C is a cross-sectional view of a portion of a housing of the positioning device of FIGS. 16A-16B.

FIG. 17A is a cutaway perspective view of another embodiment of the present positioning devices.

FIG. 17B is a side view of another embodiment of the present protruders that includes the positioning device of FIG. 17A.

FIGS. 18A-18C are a flow diagrams of example operations for validating operation of an oral appliance titration system.

FIGS. 19A-19C are flow diagrams of example operations for identifying a patient as a candidate for oral appliance therapy.

FIG. 20 is an example chart for displaying results of an obstructive sleep apnea hypnogram titration study.

FIG. 21 is an example hypnogram for displaying results of an obstructive sleep apnea therapy titration study.

FIG. 22 is a block diagram of an example computing device.

DETAILED DESCRIPTION

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art. Methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present disclosure. While implementations will be described for performing system validation and providing predictive criteria during remote titration of mandibular protrusion, it will become evident to those skilled in the art that the implementations are not limited thereto, but are applicable for performing system validation and/or providing predictive criteria during other types of obstructive sleep apnea therapy studies. Other types of obstructive sleep apnea therapy include, but are not limited to, PAP therapy, vacuum therapy, nasal vents (nasal EPAP), nasal valve dilation, etc.

The term “coupled” is defined as connected, although not necessarily directly, and not necessarily mechanically; two items that are “coupled” may be integral with each other. The terms “a” and “an” are defined as one or more unless this disclosure explicitly requires otherwise. The terms “substantially,” “approximately,” and “about” are defined as largely but not necessarily wholly what is specified, as understood by a person of ordinary skill in the art.

The terms “comprise” (and any form of comprise, such as “comprises” and “comprising”), “have” (and any form of have, such as “has” and “having”), “include” (and any form of include, such as “includes” and “including”) and “contain” (and any form of contain, such as “contains” and “containing”) are open-ended linking verbs. As a result, a method that “comprises,” “has,” “includes” or “contains” one or more steps possesses those one or more steps, but is not limited to possessing only those one or more steps. For example, in a method that comprises adjusting the initial relative position of a lower dental appliance and an upper dental appliance, and relatively displacing the lower dental appliance and the upper dental appliance: the method includes the specified steps but is not limited to having only those steps. For example, such a method could also include determining an optimal mandibular displacement for a patient. Likewise, an apparatus that “comprises,” “has,” “includes” or “contains” one or more elements possesses those one or more elements, but is not limited to possessing

only those elements. For example, in a mandibular protruder that comprises an upper dental appliance and a lower dental appliance, the mandibular protruder includes the specified elements but is not limited to having only those elements (e.g., such a protruder could also have a drive motor).

Further, a device or structure that is configured in a certain way is configured in at least that way, but it can also be configured in other ways than those specifically described.

Referring to FIGS. 1-6B and 7, one embodiment is shown of the present mandibular protruders 10 that comprises an upper mounting bracket 12, and a lower mounting bracket 14. Upper mounting bracket 12 may incorporate an upper dental appliance 18, and lower mounting bracket 12 may incorporate a lower dental appliance 20. For example, in the embodiment shown upper mounting bracket 12 has an upper dental appliance 18 that includes a dental tray, and lower mounting bracket 14 has a lower dental appliance 20 that includes a lower dental tray. In the embodiment shown, upper mounting bracket 12 includes an elongated planar portion that extends from a first end coupled to upper dental appliance 18 to a second end that is configured to be coupled to (and is shown coupled) to device 19 (e.g., via connector 46); and lower mounting bracket 14 has an elongated planar portion that extends from a first end coupled to lower dental appliance 20 to a second end that is configured to be coupled to (and is shown coupled) to device 19 (e.g., via connector 50).

As shown, for example, in FIGS. 3A-3B, lower mounting bracket 14 may be secured to upper mounting bracket 12 by a connection system that allows at least relative motion of lower mounting bracket 14 and upper mounting bracket 12 in an anterior-posterior direction 27. Anterior-posterior direction generally refers to the direction that extends between a user's anterior (e.g., chin) and a user's posterior (e.g., spine). In some embodiments, lower mounting bracket 14 may be connected to upper mounting bracket 12 for relative linear movement. For example, brackets 12 and 14 may be secured and/or coupled to one another by a connection system 22, (e.g., in the embodiment shown, a rail system 22) that is configured to couple upper mounting bracket 12 to lower mounting bracket 14. In some embodiments, rail system 22 is configured to couple upper mounting bracket 12 to lower mounting bracket 14 such that relative motion of lower mounting bracket 14 and upper mounting bracket 12 is substantially prevented in a lateral direction (e.g., by sides 24 and 26). In the embodiment shown, rail system 22 is configured to constrain relative motion of lower mounting bracket 14 and upper mounting bracket 12 to linear motion in the anterior-posterior direction (indicated by arrows 27 in FIG. 1A). For example, in the embodiment shown, protruder 10 comprises a rail system 22 that is configured to couple upper mounting bracket 12 to lower mounting bracket 14 such that relative motion of the lower mounting bracket and the upper mounting bracket is constrained to linear motion in anterior-posterior direction 27.

In the embodiment shown, rail system 22 comprises portions of one or both of upper and lower mounting brackets 12 and 14, respectively, and/or may otherwise be configured act as a slide guidance mechanism (e.g., to allow accurate anterior/posterior (A-P) positioning of the upper dental appliance 18 with respect to the lower dental appliance 20). In the embodiment shown, rail system 22 is configured such that if upper mounting bracket 12 is coupled to lower mounting bracket 14, relative motion of upper mounting bracket 12 and lower mounting bracket 14 is constrained to linear motion in the A-P direction (e.g., such

that rail system 22 prevents vertical and lateral relative movement of the mounts 12 and 14 and thereby appliances 18 and 20). In some embodiments, rail system 22 can be configured to provide or permit telescopic movement. Rail system 22 may comprise a portion of one of lower mounting bracket 14 and the upper mounting bracket 12 configured to wrap and/or wrapping at least partially around a portion of the other of lower mounting bracket 14 and upper mounting bracket 12 if upper mounting bracket 12 is coupled to lower mounting bracket 14, as shown in FIGS. 3A-3B. For example, in the embodiment shown, a portion of lower mounting bracket 14 is configured to wrap around a portion of upper mounting bracket 12 (e.g., such that the portion of lower mounting bracket 14 that is configured to wrap around the portion of upper mounting bracket 12 is coupled in fixed relation to lower mounting bracket 14, and is configured to slidably engage upper mounting bracket 14).

For example, in the embodiment shown in FIGS. 3A and 3B, lower mounting bracket 14 includes wrap-around edges 24 and 26 along a subsection of the length of lower mounting bracket 14 that are configured to wrap around upper mounting bracket 12 such that upper mounting bracket 12 can slide relative to lower mounting bracket 14 between edges 24 and 26, if lower mounting bracket 14 is coupled to upper mounting bracket 12. For example, in the embodiment shown, edges 24 and 26 are configured to provide a channel in which upper mounting bracket 12 can slide relative to lower mounting bracket 14. Edges 24 and 26 may include and/or be partially defined by guides 23 (e.g., a plurality of guides that extend from sides 24 and 26 over the top of upper mounting bracket 12 when upper and lower mounting brackets 12 and 14 are coupled or assembled), which may, for example, be extensions of the respective bracket 12 or 14. In the embodiment shown, a plurality of guides 23 extend from each of sides 24 and 26. For example, at least two guides 23 on at least one of (e.g., both of) sides 24 and 26 are spaced apart to discourage (e.g., independently of a drive motor or adjustment mechanism) vertical rotation of upper mounting bracket 12 relative to lower mounting bracket 14. Similarly, sides 24 and 26 each extends between two spaced-apart points (e.g., has a length) to discourage (e.g., independently of a drive motor or adjustment mechanism) horizontal rotation of upper mounting bracket 12 relative to lower mounting bracket 14. As illustrated, for example, in FIGS. 1A, 3B, and 7, rail system 22 is configured to act as a captive enclosure that aligns upper and lower mounting brackets 12 and 14 (and thereby dental appliances 18 and 20), and prevents relative movement of the brackets in a coronal dimension (indicated by arrows 28 in FIG. 1A), and, in the embodiment shown, prevents relative movement of the brackets in a lateral dimension (indicated by arrows 30 in FIG. 7), thereby allowing relative motion of the mounting brackets 12, 14 only in the A-P dimension or direction 27.

A-P dimension or direction 27 generally refers to a dimension or direction that extends from the incisors posteriorly in the occlusal plane (e.g., when protruder is coupled to a patient for use, as described below). A-P direction is not absolute, and instead corresponds to the longitudinal axis of upper mounting bracket 12 and/or the longitudinal axis of lower mounting bracket 14 (which are parallel in the embodiment shown). Lateral dimension or direction 30 generally refers to an axis perpendicular (at a right angle to) A-P dimension 27 and that is also in the occlusal plane. The vertical (or Coronal) dimension or direction 28 refers to an axis that is at right angles to the A-P and lateral directions, in the cranial-caudal direction and parallel to the separation between the occlusal planes. (and may be typically con-

ceived of as passing through the incisors). The dimensions or directions 27, 28, and 30 correlate to when mandibular protruder 10 is positioned in a user's mouth (not shown) and, as noted above, can be related to the longitudinal axes of upper and lower mounting brackets 12 and 14, respectively, for the embodiment shown of protruder 10.

Rail system 22 may, in some embodiments, be configured to completely restrict lateral motion by reducing the tolerance between brackets 12 and 14 (e.g., configuring brackets 12 and 14 to fit together more or very closely, such as, for example, via rail system 22). In other embodiments, rail system 22 can be configured to allow some lateral relative motion of or between upper mounting bracket 12 and lower mounting bracket 14 by increasing the tolerance between brackets 12 and 14 (e.g., configuring brackets 12 and 14 to fit together more or very closely, such as, for example, via rail system 22). In some embodiments, increased lateral motion may also be afforded by pairing upper mounting bracket 12 and/or lower mounting bracket 14 (e.g., rail system 22) with a connector (not shown) that is configured to permit some rotation around coronal dimension or direction 28. In the embodiment shown, the upper side of lower mounting bracket 14 faces and the lower side of upper mounting bracket 12 such that that they can slide in relation to each other in the anterior-posterior (A-P) dimension 27.

In some embodiments, at least one of brackets 12 and 14 may be flexible to accommodate assembly of rail system 22. For example, upper mounting bracket 12 may be configured to be flexible such that upper mounting bracket 12 can be compressed perpendicular to A-P direction 27 to reduce its width in direction 30 such that upper mounting bracket 12 can be placed between sides 24 and 26 of lower mounting bracket 14, and the compression released such that upper mounting bracket 12 returns to its original shape and extends under guides 23 of lower mounting bracket 14. Alternatively, upper and lower mounting brackets 12 and 14 can be coupled or assembled by sliding upper mounting bracket 12 from anterior to posterior in A-P direction 27 such that upper mounting bracket 14 extends between sides 24 and 26 and under guides 23. In some embodiments, increased vertical relative motion can be permitted between upper mounting bracket 12 and lower mounting bracket 14, such as, for example, by increasing the tolerances therebetween (e.g., between guides 23 and upper mounting bracket 12), omitting guides 23 such that the rail system includes sides 24 and 26 to restrict or constrain lateral movement but does not include guides 23 to restrict or constrain vertical relative movement, and/or the like. In some embodiments, the rail system can comprise, for example, a single rail (e.g., a single vertical member similar to side 24 or 26) extends from the middle of lower mounting bracket 14, through a slot in upper mounting bracket 12, and/or having a guide (e.g., 23) extending laterally to one or both sides of the slot, such that the rail system is configured to constrain lateral and/or vertical relative motion of upper mounting bracket 12 and lower mounting bracket 14.

In some embodiments, protruder 10 comprises a relative position indicator, such as scale 32 and pointer 34, for indicating (configured to indicate) relative position of upper mounting bracket 12 and lower mounting bracket 14 (and/or lower dental appliance 20 and upper dental appliance 18) if lower mounting bracket 14 is coupled to upper mounting bracket 12. As used in this disclosure, relative motion and relative position of upper mounting bracket 12 (and upper dental appliance 18) and lower mounting bracket 14 (and lower dental appliance 20) generally refers to motion or position of lower mounting bracket 14 relative to upper

mounting bracket 12 (and/or vice versa). In the embodiment shown, at least a portion of the relative position indicator is integral with rail system 22 (e.g., pointers 34 are integral with sides 24 and 26 and configured to function similarly to guides 23). More particularly, in the embodiment shown in FIG. 7, the relative position indicator comprises: scale 32 coupled to upper mounting bracket; and at least one pointer 34 (e.g., two pointers 34) coupled to lower mounting bracket 12. In this embodiment, the relative position indicator (e.g., pointer 34 and scale 32) is configured such that if upper mounting bracket 12 is coupled to lower mounting bracket 14 such that pointer 34 is within a range of scale 32, pointer 34 will indicate a position of lower dental appliance 14 relative to upper dental appliance 12 (e.g., a relative position therebetween). In some embodiments, scale 32 is integral with upper mounting bracket 12. In some embodiments, scale 32 comprises a GEORGE GAUGE scale.

The relative position indicator may be at least partially formed of parts, such as pointer 34, of the rail system 22. The relative position indicator may comprise quantitative elements, such as the markings that make up (are included in) scale 32. The relative position indicator allows the relative displacement between appliances 18 and 20 to be accurately measured by measuring the relative displacement between upper and lower mounting brackets 12 and 14. Pointer 34 may be an arrow-shaped guide, as shown in FIG. 7.

In the embodiment illustrated, mounting brackets 12 and 14 cooperate to display a graduated measuring system, located for example on the struts (elongated portions) of brackets 12 and 14, that allows a physician or other user to measure the relative position of appliances 18 and 20 (for or unique to a patient) during a fitting or other procedure for the patient. Scale 32 may provide a reference value of retrusion of the lower jaw, for example indicative of a point where the appliances 18 and 20 are positioned with the patient's upper and lower incisors vertically aligned. Scale 32 may be designed to measure relative movement of the appliances 18 and 20 with respect to each other in the A-P dimension on either side of the reference value. In one embodiment, a protrusive position of the mandible relative to zero corresponds to a positive number and a retrusive position of the mandible relative to zero corresponds to a negative number. The exact location of the reference value for a given patient may, in some embodiments, be experimentally determined, and may or not be indicated by the zero numeral on scale 32. However, in some embodiments, the zero numeral may be configured to indicate the vertical alignment of appliances 18 and 20 (that appliances 18 and 20 are aligned, as shown in FIG. 2). In other embodiments, scale 32 may vary. For example, the reference position may be indicated by the numeral 10, retrusive values may occupy or be indicated by numerical values in the range 0-10, and protrusive values occupy or be indicated by numerical range 10-20.

FIGS. 8 and 9 depict alternate embodiments of relative position indicators. In the embodiment of FIG. 8, lower bracket 14 comprises a scale 32 comprising ribbed elements 36, and upper mounting bracket 12 comprises a pointer 34 defined on a guide 23. Ribbed elements 36 may allow taking measurements to be more user-friendly, such as when reference pointer 34 is spaced vertically from a scale surface 38, as shown. For example, in the embodiment shown, ribbed elements 36 extend upward from scale surface 38 such that the tops of ribbed elements 36 are closer to pointers 34. In this embodiment, scale surface 38 is inserted in between wrap-around edges 39 and 40 of lower mounting

bracket 14 and/or between pointer(s) 34 of upper bracket 12. Scale surface 38 may be elongated and/or flattened to improve visibility.

In the embodiment of FIG. 9, the relative position indicator comprises: a scale 32 coupled to upper mounting bracket 12; and a window 41 extending through lower mounting bracket 14. More particularly, in this embodiment, upper mounting bracket 12 comprises a reference window 41 for viewing only a portion of a scale 32. In this embodiment, scale 32 is coupled to (e.g., integral with) an upper surface 42 of lower mounting bracket 14. In the embodiment shown, the relative position indicator is thus configured such that if upper mounting bracket 12 is coupled to lower mounting bracket 14 such that window 41 is within a range of scale 32 (such that a portion of scale 32 is viewable through window 41), scale 32 is viewable through window 41 to indicate a position of lower dental appliance 14 relative to upper dental appliance 12. In the embodiment shown, the relative position indicator further comprises a reference pointer 34 that is illustrated by markings 44 and/or includes slits 44 on one or both sides of window 41 such that if scale 32 is viewable through window 41, pointer 34 will indicate a position of lower dental appliance 20 relative to upper dental appliance 18. In other embodiments, pointer 34 may also or alternatively be digital, such as, for example a sensor and readout, a barcode reader-type electronic detection device. Other embodiments of reference pointer 34 may include a physical indicator that extends from rail (side 24 or edge surface 39) to rail (side 26 or edge surface 40) as a bar, or a pointer that comes up from the lower appliance 20 through a slot in the upper appliance 18.

Referring again to FIGS. 1-7, in the embodiment shown, protruder 10 comprises a drive motor 16 configured to effect or for effecting relative displacement of lower mounting bracket 14 and upper mounting bracket 12. More than one motor 16 may be used to effect such displacement. For example, in some embodiments (not shown), the present mandibular protruders can comprise a separate motor for each of brackets 12 and 14. In the embodiment shown, motor 16 comprises a linear actuator 17 configured to effect relative displacement of lower mounting bracket 14 and upper mounting bracket 12. In some embodiments, motor 16 is coupled more directly to one of upper mounting bracket 12 and lower mounting bracket 14 than to the other of upper mounting bracket 12 and lower mounting bracket 14. For example, in the embodiment shown, motor 16 is coupled more directly to upper mounting bracket 12 than the lower mounting bracket 14 (e.g., as a result of motor 16 being actuated, upper mounting bracket 12 and upper dental appliance 18 move relative to motor 16, while lower dental appliance 20 and lower mounting bracket 14 are not moved relative to motor 16). In other embodiments, motor 16 can be coupled more directly to lower mounting bracket 14.

In some embodiments motor 16 can be coupled to one of brackets 12 and 14 by a connector (or shaft or rod) 46, such as an actuator arm or rod of motor 16. The other of brackets 12 and 14 may be coupled or mounted directly or indirectly to motor 16 (e.g., to the body of motor 16 instead of linearly actuated connector 46), such that if the more-directly coupled bracket 12 or 14 is extended or retracted by motor 16, relative displacement is effected between appliances 18 and 20. For example, an indirect coupling may include coupling lower mounting bracket 14 to a housing of motor 16 instead of to connector 46). In the embodiment shown, connector 46 is coupled in contact with upper mounting bracket 12. In some embodiments, linear actuator 17 is configured to allow smooth and/or quiet movement bi-

directionally in a single axis (horizontal in dimension or direction 27), which may be more comfortable to a patient than a stepping motor (e.g., may be less likely to wake a patient during use of protruder 10 in sleep titration study). However, in some embodiments, motor 16 may comprise a stepping motor or may be configured to be actuated or operated in a step-wise fashion. In some embodiments, linear actuator 17 may be limited to a maximum displacement, such as 20 mm, and/or may be configured to move in smooth minimum fine increments, such as, for example, 0.2 mm increments. Linear actuator 17 may comprise, for example, a Firgelli PQ12-63-6-P motor (available from Firgelli Technologies Inc., Vancouver, B.C., CANADA) that is lightweight and has an appropriate small footprint and box form factor for the protruder 10. Motor 16 may, for example, comprise a brushless and/or direct current (DC) motor. In other embodiments, motor 16 may comprise other suitable motors or actuators, such as, for example, a hydraulic piston.

In the embodiment shown, a mandibular positioning device 19 comprises and/or houses drive motor 16. Device 19 and brackets 12 and 14 are configured such that brackets 12 and 14 can be coupled to device 19, such as, for example, with or through connectors (or shafts or rods) 46 and 52, respectively. In the embodiment shown, upper mounting bracket 12 is configured to be coupled to connector 46 (e.g., drive-motor connector 46), and lower mounting bracket 14 is configured to be coupled to connector 52 (e.g., adjustment-mechanism connector 52, as discussed in more detail below). In the embodiment shown, connector 46 is configured to couple upper mounting bracket 12 (e.g., directly) to drive motor 16, and connector 52 is configured to couple lower mounting bracket 14 to device 19 such that if drive motor 16 extends and/or retracts bracket 12, bracket 14 remains stationary relative to device 19 and the housing of motor 16. In the embodiment shown, connector 52 is parallel to connector 46.

The one of the upper and lower mounting brackets 12, 14 that is coupled to be driven by motor 16 (in the embodiment shown, upper mounting bracket 12 and upper dental appliance 18), may be coupled to the motor 16 along the anterior-posterior axis 27 such that motor 16 can be actuated or activated to displace appliance 18 along the A-P direction 27. In this way, appliances 18 and 20 can be precisely and repeatably positioned relative to one another, and thus can precisely and repeatably protrude a patient's mandible relative to the patient's maxilla. During adjustment, drive motor 16 may effect relative displacement by extending or retracting connector 46 relative to device 19 such that device 19 is configured to push or pull a patient's mandible relative to the patient's maxilla. In the embodiment shown, extending connector 46 pushes the upper bracket 12 away from device 19 and causes drive motor 16 to move away from the patient. Due to a relatively static connection between drive motor 16 and lower mounting bracket 14 (e.g., via connector 52), lower mounting bracket 14 is simultaneously pulled, thereby pulling the patient's mandible (moving the patient's lower jaw with lower mounting bracket 14). The net effect is that a patient's lower jaw may be protruded forward (in an anterior direction) by exerting a backward force (in a posterior direction) on the upper jaw.

In the embodiment shown, mandibular positioning device 19 comprises a housing 48, such as a casing 48. Drive motor 16 and related components may be enclosed in casing 48, such as, for example, to protect drive motor 16 and patient from cross infection and bacteria. In some embodiments, casing 48 may be sealed and/or may be openable or removable (e.g., through an access door, such as shown on the back

of housing 48, which may be attached and/or removable via screws, clips, tabs, or the like). For example, FIGS. 14C and 17C depict alternate embodiments of housings suitable for use with embodiments of the present devices 19. In some embodiments, casing 48 may be applied as a protective spray coating. In the embodiment shown (e.g., FIG. 2A), casing 48 houses or contains drive motor 16 and permits connectors 46 and 52 to extend out of casing 48. In the embodiment shown, connector 46 of motor 16 is configured to be coupled to a mounting bracket of a first dental appliance (e.g., upper mounting bracket 12 having upper dental appliance 18); and connector 52 is configured to be coupled to a mounting bracket of a second dental appliance (e.g., lower mounting bracket 14 having lower dental appliance 20).

In some embodiments, protruder 10 (e.g., device 19) comprises an initial position adjustment mechanism 50. In embodiments in which drive motor 16 is coupled more directly to one of brackets 12 and 14 (bracket 12 in the embodiment shown), the other of brackets 12 and 14 (bracket 14 in the embodiment shown) may be coupled to adjustment mechanism 50 (e.g., through connector 52). Initial position adjustment mechanism 50 is configured to be actuated to adjust the relative position of lower mounting bracket 14 and upper mounting bracket 12 (e.g., independently of drive motor 16). More particularly, in the embodiment shown, housing 48 is coupled to drive motor 16 and initial position adjustment mechanism 50; drive motor 16 is coupled between housing 48 and upper mounting bracket 12, and/or configured to adjust the relative position of lower mounting bracket 14 and upper mounting bracket 12 by adjusting the position of upper mounting bracket 12 relative to housing 48; and/or initial position adjustment mechanism 50 is coupled between housing 48 and lower mounting bracket 14, and/or configured to be actuated to adjust the relative position of lower mounting bracket 14 and upper mounting bracket 12 by adjusting the position of lower mounting bracket 14 relative to housing 48.

In this embodiment, protruder 10 is configured such that the position of upper dental appliance 18 with respect to (relative to) lower dental appliance 20 can be adjusted to a reference point (e.g., as a starting point from which a study of or for a patient can commence). This pre-adjustable reference point may be configured at a calibration time or step (e.g., before beginning a study), and/or then fixed in place before the study for the duration of the study. This reference point may be used to effectively zero or calibrate the device to a patient-specific reference retracted position. In some embodiments, the relative position indicator may be adjustable to point to zero on scale 32 when the protruder 10 is in the reference position. For example, in some embodiments, lower mounting bracket 14 can comprise an adjustable pointer 34 that can be adjusted or slid relative to lower mounting bracket 14 (e.g., relative to side 24 or 26) and/or upper mounting bracket 14 can comprise scale 32 that can be adjusted or slid relative to upper mounting bracket 12. Adjustable attachment of lower mounting bracket 14 to the housing of motor 16 can be accomplished by a variety of methods and/or with a variety of structures or configurations.

For example, in the embodiment shown (e.g., FIGS. 6A and 6B), initial position adjustment mechanism 50 comprises a manually operable element, such as, for example, a screw 54 and/or a knob 56 coupled to screw 54 such that knob 56 can be rotated outside housing or casing 48 to rotate screw 54 inside housing 48. In this way, adjustment mechanism 50 is configured such that turning a rotational external

fixture, such as knob 56, rotates screw 54 to mechanically adjust the position of connector 54 (and thereby lower dental appliance 20) along the anterior-posterior axis 27 (FIG. 1A). This allows the start or initial relative position of the appliances 18, 20 to be accurately and reproducibly achieved before initiating a study of a patient. Screw 54 (and thereby knob 56) can be coupled to an end 53 of connector 54. For example, end 53 of connector can be provided with female or internal threads corresponding to male or external threads of screw 54, and screw 54 can be rotatably coupled to housing 48 such that screw 54 is linearly fixed relative to housing 48, such that rotation of screw 54 will translate into linear displacement of connector 52. As shown in FIGS. 1A and 1B, the depicted initial position adjustment mechanism 50 is configured to allow positioning of lower appliance 20 to a retracted position in which upper appliance 18 is retracted relative to housing 48 (e.g., in which lower mounting bracket 14 is as close to housing 48 as permitted). As shown in FIG. 1C, when upper appliance 18 fully retracted and lower appliance 20 fully is extended, the full stroke of the drive motor 16 (FIG. 6A) is available for protruding a patient's mandible from the fully retracted position. FIG. 1A shows both of appliances 18 and 20 fully retracted, while FIG. 1B shows the protruder 10 in a maximally protruded position or configuration in which appliance 18 is fully extended and appliance 20 is fully retracted relative to device 19 (housing 48).

In some embodiments, connector 52 and/or housing 48 are configured to resist rotation of connector 52 relative to housing 48. For example, in the embodiment shown, connector 52 comprises longitudinal protrusions 55 that are aligned with the longitudinal axis of connector 52, and housing or casing 48 comprises grooves 57 configured to receive protrusions 55 such that connector 52 can move linearly relative to housing 48 but is constrained to linear motion (e.g., such that protrusions 55 and grooves 57 cooperate to prevent connector 52 from rotating relative to housing 48). In other embodiments, other initial position adjustment mechanisms may be used, such as, for example, motorized mechanisms. In the embodiment shown, adjustment mechanism 50 further comprises a locking nut 67 configured to prevent screw 54 from moving in the A-P direction relative to housing 48. For example, in some embodiments, the threads of nut 67 are provided or coated with an adhesive or the like such that screw 54 can be threaded into nut 67 to assemble adjustment mechanism 50 and/or device 19, but then becomes fixed relative to nut 67 to maintain the linear position of screw 54 relative to housing 48 while still permitting rotation of screw 54 relative to housing 48.

Additionally, in the embodiment shown, housing 48 has a sidewall with at least a first opening (corresponding to connector 46) and a second opening (corresponding to connector 52). In this embodiment, housing 48 is coupled to drive motor 16 and adjustment mechanism 50 such that housing 48 encloses at least a portion of each of drive motor 16 and adjustment mechanism 50, and such that drive-motor connector 46 extends out of housing 48 through the first opening, and adjustment-mechanism connector 52 extends out of housing 48 through the second opening. In the embodiment shown, adjustment mechanism 50 is configured to linearly adjust the position of adjustment-mechanism connector 52; and drive motor 16 is configured to linearly move drive-motor connector 46 in a direction substantially parallel to the direction in which adjustment mechanism 50 can adjust adjustment-mechanism connector 52.

As shown FIG. 3A, and as noted above, upper dental appliance 18 may comprise an upper dental tray 58, and lower dental appliance 20 may comprise a lower dental tray 60. Appliances 18 and 20 may include upper and lower arches, respectively, that fit into a patient's mouth and/or receive a patient's teeth (e.g., a portion of a patient's teeth) to hold or couple to the patient's jaws. Mounting brackets 12 and 14 extend out from with appliances 18 and 20, respectively. In some embodiments of the present mandibular protruders, upper dental appliance 18 is integral with, for example molded as a part of, upper mounting bracket 12. Similarly, in some embodiments, lower dental appliance 20 is integral with, for example molded as a part of, lower mounting bracket 14. In other embodiments, appliances 18 and 20, and their respective mounting brackets 12 and 14 may be coupled together as separate parts. Appliances 18 and 20 may be U-shaped disposable or non disposable appliances for a patient's upper and lower jaws, respectively. In some embodiments (e.g., FIG. 10), appliances 18 and 20 may comprise at least a partial mould of a patient's teeth. For example, appliances 18 and 20 may be filled with a quick-set material, such as boil-and-bite insert 62, which may be used to take fast custom impressions. For example, materials such as a silastic impression material (e.g., PolyFil.™ TransBite available from SciCan.™ Medtech AG, Cham, Switzerland) and/or a thermoplastic impression material may be used. In some embodiments (e.g., embodiments in which appliances 18 and/or 20 (e.g., trays 58 and/or 60) are intended to be disposable, the present kits can comprise a positioning device 19 and a plurality of appliances 18 and/or 20 (e.g., trays 58 and/or 60).

As discussed below, some embodiments comprise: dental impression material configured to be coupled to at least one of the upper dental appliance and the lower dental appliance, the dental impression material configured to be imprinted with and maintain an impression of a patient's teeth. A patient may be fitted with appliances 18 and 20 in his or her natural resting or normal bite position, in order to establish the reference position in some cases. The position of appliances 18 and 20 may be secured together, such as by clipping together, to preserve this relative position, such as the natural resting or normal bite position of upper and lower appliances 18 and 20. Optionally, the position of the appliances 18 and 20 may be secured together, such as by clipping together, to preserve the position determined to be an optimal mandibular displacement (e.g., a target therapeutic distance) determined in a titration study. In the embodiment shown, tray walls 63 and 65 of appliances 18 and 20, respectively, include slits 64 throughout to import greater flexibility and/or to permit dental impression material to extrude or extend through slits 64 to improve stability of the dental impression material (e.g., insert 62) relative to appliances 18 and 20. Walls 63 and 65 may also provide improved retention of insert 62. Appliances 18 and 20 may also be configured to maximize fit and comfort, and minimize encroachment on lingual space. Front portions 66 and 68 of appliances 18, 20 may be narrower than respective back or lateral portions 70 and 72 (e.g., to fit the natural size of the teeth). In the embodiment shown, appliances 18 and 20 are each configured to permit lateral portions (e.g., 70, 72) to flex relative to the front portions 66 and 68 (e.g., via slits between the front portions and the lateral portions. Inner tray walls 63A and 65A may be half the height of outer tray walls 63B and 65B of appliances 18 and 20, respectively, (e.g., to provide a better fit and comfort and/or provide greater stability for upper appliance 18 during movement (e.g., upon activation of motor 16). In some embodiments,

appliances **18** and **20** may be designed and/or configured to such that the molar arms (lateral portions) of the trays spring laterally (are biased in a lateral, outward direction) so the inner wall of the trays are applied firmly (tend to press against) to the lingual surface of the molars and thereby minimize encroachment into the lingual space. In some embodiments, appliances **18** and **20** are flexible and/or smaller in size than existing dental trays (e.g., to improve comfort or fit for a patient). As illustrated (e.g., in FIGS. **1A-1C** and **6A-6B**), upper mounting bracket **12** may include a planar portion extending anteriorly along a plane defined by inferior (lower) surface or aspect **70** of upper dental appliance **18** and/or lower mounting bracket **14** may include a planar portion extending anteriorly along a plane defined by superior (upper) aspect or surface **72** of lower dental appliance **20**, as shown.

In the embodiment shown, and as noted above, appliances **18** and **20** are coupled to mandibular positioning device **19** through brackets **12** and **14**, respectively. In the embodiment shown, upper mounting bracket **12**, lower mounting bracket **14**, and rail system **22** are configured to be removably coupled to drive motor **16** (and/or positioning device **19**). More particularly, in the embodiment shown, drive-motor connector **46** has a longitudinal axis that is substantially parallel to the direction of actuation (e.g., A-P direction **27**) of drive motor **16**, and one of upper mounting bracket **12** and lower mounting bracket **14** (as shown, upper mounting bracket **12**) is configured to be coupled to drive-motor connector **46** such that the longitudinal axis of the one of upper mounting bracket **12** and lower mounting bracket **14** (as shown, upper mounting bracket **12**) is substantially parallel to (and, in some embodiments, co-linear with) the longitudinal axis of drive-motor connector **46**. As shown in FIGS. **3A** and **3B**, in some embodiments, such as the embodiment shown, mandibular protruder **10** may include an upper release mechanism (e.g., a nut **74** and bolt **76** arrangement for passing through bracket **12** and connector **46**), for release of upper dental appliance **18** from device **19** (shown in FIG. **4**). Similarly, mandibular protruder **10** may incorporate a lower release mechanism (e.g., a nut **78** and bolt **80** arrangement for passing through bracket **14** and connector **52**), for release of lower dental appliance **20** from mandibular positioning device **19**. In other embodiments, nuts **74** and/or **78**, and/or bolts **76** and/or **80**, may include and/or may instead comprise any suitable fastener, such as, for example, a wing-nut or wing-bolt that can be tightened or loosened by hand (without additional tools), a pin and/or a cotter pin, and/or the like. In some embodiments, upper mounting bracket **12** and/or lower mounting bracket **14** may be threaded on at least one side of connector **46** or **52**, such that no nuts are needed to tighten or hold bolts **76**. In some embodiments, bolts **76** and/or **80** comprise screws (not shown) such that the nuts are omitted.

In some embodiments, upper mounting bracket **12** is configured to be coupled to a connector (e.g., **46** or **52**) of an initial adjustment mechanism **50** or a drive motor **16**, and lower mounting bracket **14** is configured to be coupled to a connector (e.g., **46** or **52**) of an initial adjustment mechanism **50** or a drive motor **16**. For example, in the embodiment shown, upper mounting bracket is configured to be coupled to connector **46**, and lower mounting bracket **14** is configured to be coupled to connector **52**. More particularly, in the embodiment shown, adjustment-mechanism connector **46** includes a longitudinal axis, a proximal portion **82A** having a first cross-section, and a distal portion **82B** having a second cross-section that is different than the first cross-section; and drive-motor connector **52** includes a longitudi-

nal axis, a proximal portion **84A** having a first cross-section, and a distal portion **84B** having a second cross-section that is different than the first cross-section. More particularly, in the embodiment shown, first cross-sections of proximal portions **82A** and **84A** are circular, and second cross-sections of distal portions **84A** and **84B** have parallel sides (e.g., are similar to rectangles with curved upper and lower perimeters). In some embodiments, connectors **46** and **52** are configured with different sizes and/or cross-sectional shapes so that at least one of connectors **46** and **52** will only couple to one of upper mounting bracket **12** and lower mounting bracket **14**. For example, in some embodiments, distal portion **82B** of connector **46** is wider than distal portion **84B** of connector **52**. In the embodiment shown, adjustment-mechanism connector **52** includes a hole **81** extending through distal portion **84B** transverse to the longitudinal axis of adjustment-mechanism connector **52**; and drive-motor connector **46** includes a hole **77** extending through distal portion **82B** transverse to the longitudinal axis of drive-motor connector **46**. In this embodiment, connectors **46** and **52** are configured to be coupled to brackets **12** and **14** having respective recesses that correspond to the shape of connectors **46** and **52** (e.g., to improve the strength of connection to between brackets **12** and **14**, and connectors **46** and **52**, respectively).

Similarly, as illustrated, for example, in FIGS. **3A** and **3B**, upper mounting bracket **12** has a longitudinal axis and a recess **73** configured to receive a portion of connector **46**. Recess **73** has an outer portion with a first cross-section (corresponding to first cross-section of proximal portion **82A**), an inner portion having a second cross-section (corresponding to second cross-section of distal portion **82B**) that is different than the first cross-section, and a hole **75** extending transverse to the longitudinal axis of upper mounting bracket **12**, and through upper mounting bracket **12** across the inner portion of recess **73**. Similarly, lower mounting bracket **14** has a longitudinal axis and a recess **83** configured to receive a portion of connector **52**. Recess **75** has an outer portion with a first cross-section (corresponding to first cross-section of proximal portion **84A**), an inner portion having a second cross-section (corresponding to second cross-section of distal portion **84B**) that is different than the first cross-section, and a hole **79** extending transverse to the longitudinal axis of lower mounting bracket **14**, and through lower mounting bracket **14** across the inner portion of recess **75**.

To couple dental appliance **18** to connector **46**, connector **46** may be slid into recess **73**, which may be molded as part of bracket **12**. Bolt **76** may then be passed through hole **75** of bracket **12**, and hole **77** of connector **46**. Nut **74** may then be used to secure bolt **76** in place. Similarly, to couple appliance **20** to connector **52**, connector **52** may first be slid into recess **83**, which may be molded as part of bracket **14**. Bolt **80** may then be passed through hole **79** of bracket **14**, and hole **81** of connector **52**. Nut **78** is then used to secure bolt **80** in place. In the embodiment shown, holes **77** and **81** pass through the width of connectors **46** and **52**, respectively, and align with holes **75** and **79** in recesses **73** and **83**, respectively. Nut **74** can be tightened sufficiently to prevent vertical tilting of upper tray **18**, or can be tightened to a degree that permits some vertical tilting of tray **18** (e.g., within the tolerances of rail system **22**). Bolt **76** and **80** sizing may be chosen to ensure a tight fit with respective holes **75** and **79** to ensure that little or no movement is possible between device **19** and appliances **18** and **20** (e.g., to rigidly fixed the components of protruder **10** together). Tilting may also be restricted by rail system **22** (e.g.,

portions of mounting brackets **12** and **14**, and/or appliances **18** and **20**, may be flush and planar to each other). The encapsulation of connectors **46** and **52**, by recesses **73**, **83**, respectively, provide structures that are configured to prevent rotation about coronal axis **28**. In these and other embodiments, appliances **18** and **20** and brackets **12** and **14** are disposable. Other releasable connection points may be used, such that at least appliances **18** and **20** may be disposable. In some embodiments, protruder **10** itself is fully or partially disposable. Various components of protruder **10** (e.g., brackets **12** and **14**, connectors **46** and **52**, and/or housing **48**) can comprise acetal-based plastics, such as, for example, Polyoxymethylene (POM).

The general operation of the mandibular protruder **10** may be illustrated with reference to FIGS. **1A-C**. Beginning at the retruded position shown in FIG. **1A**, a protrusion of the mandible is achieved by extending connector **46**, thereby exerting an inward force on upper dental appliance **18**. A comparable and opposite protruding force is thus exerted on lower dental appliance **20**. As shown in FIG. **1B**, these forces cause protrusion of the mandible with respect to the maxilla and the rest of the skull (e.g., through protrusion of lower dental appliance **20** relative to upper dental appliance **18**). As shown in FIG. **1C**, for retrusion of the mandible, the reverse occurs: connector **46** retracts, and thereby exerts an outward or pulling force on upper appliance **18** and an opposite pushing or retruding force on lower appliance **20**. As described above, this will, for most patient's, cause a retrusion of the mandible.

An oral appliance titration study includes patient physiologic data collected from either a portable monitor or a polysomnogram (PSG) and position data collected from the titration device (e.g., the mandibular protruder **10** discussed above). This data is collected, scored and interpreted to provide the test results (e.g., prediction of success and amount of protrusion). In some implementations, the mandibular protruder can be a remote-control mandibular protruder (RCMP). Relative displacement of the RCMP during use is actuated or controlled by a motor or other actuator instead of by physical actuation of the oral appliances or mounting brackets by a user. Remote control of the RCMP is discussed in further detail below. In contrast to titration systems that are manually adjusted (i.e., where the scale can be read directly from the titration device), an unattended titration (such as the RCMP, for example) requires that a control system (e.g., a workstation **92** or controller **94** discussed below, for example) is accurately reading the physical position of the device. To accomplish this, a motor function test and calibration procedure can be executed at the start of each oral appliance titration study.

Referring now to FIG. **18A**, example operations for validating operation of an oral appliance titration system are shown. In some embodiments, the oral appliance titration system includes the RCMP discussed above. For example, as discussed above, the mandibular protruder **10** can be a mandibular protruder as shown in any of FIGS. **1A-1C**, **2**, **6A-6B**, **10** and **14A-14B**. In particular, the mandibular protruder **10** can include the upper mounting bracket **12** having the upper dental appliance **18** and the lower mounting bracket **14** having the lower dental appliance **20**. Additionally, the mandibular protruder **10** can include the drive motor **16** that is configured to effect relative displacement between the upper and lower mounting brackets **12**, **14**. In some implementations, the drive motor **16** includes the linear actuator **17** that can effect relative displacement. At **1802**, calibration data for the drive motor **16** is received. The drive motor **16** can be provided with calibration data by the

manufacturer. For example, the drive motor **16** can be calibrated to achieve a high degree of accuracy (e.g., +/-0.5 mm) during the manufacturing process. In some implementations, the calibration data can be a code defining the response of the drive motor **16**. For example, the code can define the response of the drive motor **16** within a predetermined tolerance. Optionally, the response of the drive motor can be linear. In some implementations, extension of the linear actuator **17** within the drive motor **16** can be measured by a voltage drop across a variable resistor. The code can be the linearity of the linear actuator **17** defined by $X=a*V+b$, where a and b are provided as a n-character string such as a 6-character string, for example. Optionally, to reduce the risk of an invalid code, the n-character string can include a check sum. Accordingly, at the beginning of an oral appliance titration study, the calibration data (i.e., the code) is received by the control system. For example, the code can be manually entered and/or loaded into the control system for a new drive motor. Alternatively or additionally, the control system can store the code for previously used drive motors. A check can then be performed to ensure that the mandibular protruder **10** is adequately described by the calibration data.

At **1804**, the mandibular protruder **10** can be commanded to a plurality of positions. Optionally, before commanding the mandibular protruder **10** to the plurality of positions, an initial position of the mandibular protruder **10** can be set. For example, the initial position adjustment mechanism **50** can be set to a fixed position such as its fully extended position, for example. In some implementations, the mandibular protruder **10** can be commanded to a plurality of predetermined positions. For example, the mandibular protruder **10** can be commanded to at least three positions such as a fully retruded position, a fully protruded position and a position between the fully retruded and fully protruded position. It should be understood that other known and fixed positions can also be used. By commanding the mandibular protruder **10** to the plurality of positions, the control system drives the actuator (e.g., the drive motor **16**) to each of the plurality of positions.

At **1806**, an actual physical position of the mandibular protruder **10** is received at each of the plurality of positions. For example, an operator can read the actual physical position of the mandibular protruder **10** from a relative position indicator such as the scale **32** and the pointer **34** of the mandibular protruder **10**, for example. The operator can then enter the actual physical position of the mandibular protruder **10** at each of the plurality of positions into the control system. At **1808**, the actual physical position mandibular protruder **10** can be compared to an expected position of the mandibular protruder **10**. In some implementations, the expected position of the mandibular protruder **10** can be a detected feedback position. For example, as discussed above, extension of the linear actuator **17** within the drive motor **16** can be measured by a voltage drop across a variable resistor. Accordingly, the expected position of the mandibular protruder **10** can be determined based on the measured voltage and the calibration data. At **1810**, it is possible to detect whether the mandibular protruder **10** is validly operating based on the results of the comparison.

Referring now to FIG. **18B**, example operations for validating operation of an oral appliance titration system according to another implementation are shown. Similarly to FIG. **18A**, calibration data for the drive motor **16** is received at **1812**, the mandibular protruder **10** is commanded to a plurality of positions at **1814** and the actual physical position of the mandibular protruder at each of the plurality of

positions is received at **1816**. Because these operations are identical to steps **1802-1806** discussed with regard to FIG. **18A**, these operations are not discussed in further detail below. At **1818**, a deviation between the actual position mandibular protruder **10** and an expected position of the mandibular protruder **10** is calculated for each of the plurality of positions. The expected position of the mandibular protruder **10** is determined similarly as discussed with regard to FIG. **18A**. For example, the expected position of the mandibular protruder **10** can be a detected feedback position. In some implementations, the deviations can be expressed as Eqn. (1) below.

$$\text{dev}_i = (F_i - 5) - (P_i - 4) \quad (1)$$

where dev_i is a deviation at one of the plurality of positions, F_i is the detected feedback position (i.e., the expected position of the mandibular protruder **10**) at one of the plurality of positions, P_i is the actual physical position of the mandibular protruder **10** at one of the plurality of positions and “5” and “4” are constants. The constants can reflect the linear actuator extension and scale reading when the upper mounting bracket **12** is flush and the initial position adjustment mechanism **50** is fully extended, for example. It should be understood that the constants can have values other than “5” and “4” depending on the linear actuator extension and scale reading.

At **1820**, a determination can be made as to whether the deviation for each of the plurality of positions is within a predetermined tolerance. In some implementations, the predetermined tolerance can be equal to the expected accuracy of the drive motor **16** (e.g., +/-0.5 mm, for example). If the deviation of each of the plurality of positions is within the predetermined tolerance, the system is valid. This is shown at **1830** in FIG. **18B**. In this case, the operator can proceed to calibrating a PSG channel without further adjustment, which is discussed in detail below with regard to FIG. **18C**. If, however, the deviation of at least one of the plurality of positions is not within the predetermined tolerance, a suggested adjustment can be calculated for the mandibular protruder **10**. In some implementations, the suggested adjustment can be an average of the deviations for the plurality of positions. For example, the suggested adjustment can be expressed as Eqn. (2) below.

$$SA = (\text{dev}_A + \text{dev}_B + \text{dev}_C) / 3, \quad (2)$$

where SA is the suggested adjustment, dev_A is the deviation at the first position, dev_B is the deviation at the second position and dev_C is the deviation at the third position.

At **1824**, a determination is made as to whether the suggested adjustment is within a predetermined range. The suggested adjustment can compensate for small variations in the linear actuator **16** and/or scale **32**. The predetermined range can be +/-2.0 mm, for example. If the suggested adjustment is within the predetermined range, then the initial position of the mandibular protruder **10** can be adjusted by the suggested adjustment at **1826**. For example, the initial position can be adjusted with the initial position adjustment mechanism **50**. Then, the operation proceeds to step **1814**, where the mandibular protruder **10** is re-commanded to the plurality of positions. Then, the validation check is re-performed after making the suggested adjustment. If, however, the suggested adjustment is not within the predetermined range, a recommendation is made to replace the mandibular protruder **10** at **1828**. In some implementations, the titration system may provide a warning and/or may prevent the operator from using the mandibular protruder if the suggested adjustment is not made.

Alternatively or additionally, a check can be performed to determine if the drive motor **16** is sufficiently linear. For example, a difference between the deviation for each of the plurality of positions and the suggested adjustment can be calculated. The difference between the deviation for each of the plurality of positions and the suggested adjustment can be expressed by Eqn. (3) below.

$$D = \text{dev}_i - SA \quad (3)$$

where D is the difference, SA is the suggested adjustment, dev_i is the deviation at one of the plurality of positions. If the difference between the deviation and the suggested adjustment for any one of the plurality of positions is greater than the predetermined tolerance, which can be equal to the expected accuracy of the drive motor **16** (e.g., +/-0.5 mm, for example), then the drive motor **16** is considered to be non-linear. In other words, the linearity of the drive motor **16** has degraded. Accordingly, a recommendation is made to replace the drive motor **16**. In some implementations, the titration system may provide a warning and/or may prevent the operator from using the mandibular protruder if the drive motor **16** is not replaced.

Referring now to FIG. **18C**, example operations for validating operation of an oral appliance titration system according to yet another implementation are shown. According to this implementation, the titration system can also include a polysomnogram (PSG), and the example operations can further include calibrating a channel of the PSG. Optionally, the channel of the PSG can be calibrated after confirming that the titration system is validly operating as discussed above. At **1842**, upper and lower limits for the mandibular protruder **10** are received. In some implementations, the upper and lower limits are patient-specific. For example, the upper and lower limits can be within an expected range of 20 mm. In some implementations, the upper limit can be approximately the fully protruded position of a patient's jaw, and the lower limit can be range from approximately the fully retruded position of the patient's jaw to the neutral position (i.e., habitual bite). Additionally, the lower limit can be the neutral position minus a predetermined offset such as 1 mm, for example. In this implementations, the titration study is performed between the neutral position minus the offset to approximately the fully protruded position because results from approximately the fully retruded position to the neutral position can be less relevant. The upper and lower limits can be provided to the patient before performing the titration study by a dentist, for example. Additionally, the upper and lower limits can be received by the control system.

At **1844**, the mandibular protruder **10** is commanded to the upper and lower limits. Then, at **1846**, an actual physical position of the mandibular protruder at each of the upper and lower limits is received. Because these operations are similar to steps **1802-1804** discussed with regard to FIG. **18A**, these operations are not discussed in further detail below. At **1848**, a deviation between the actual physical position and an expected position for the mandibular protruder **10** at each of the upper and lower limits is calculated. The expected position of the mandibular protruder **10** can be a detected feedback position, for example. Because this operation is similar to step **1818** discussed with regard to FIG. **18B**, this operation is not discussed in further detail below. At **1850**, a determination is made as to whether the channel of the PSG is calibrated. For example, if the deviation at each of the upper and lower limits are within a predetermined tolerance such as +/-0.5 mm, for example, the channel of the PSG is calibrated. If, however, the deviation at each of the

upper and lower limits are not within the predetermined tolerance such as ± 0.5 mm, for example, the channel of the PSG is not calibrated.

Alternatively or additionally, a safety check can be performed. As discussed above, upper and lower limits, which are patient-specific, are received. The upper and lower limits can define maximum amounts of protrusion or retrusion of a patient's jaw. Exceeding either the upper limit or lower limit can cause pain and/or injury to the patient. Accordingly, a determination can be made as to whether the actual physical position of the mandibular protruder is greater than the upper limit or less than the lower limit. In the event that the actual physical position is greater than the upper limit or less than the lower limit, the titration system may provide a warning and/or may prevent the operator from using the mandibular protruder.

Referring to FIGS. 11 and 12, FIG. 11 depicts a schematic of one embodiment of the present systems for carrying out a sleep titration on a patient with a mandibular protruder 10, and FIG. 12 depicts a flowchart of one method of displacing a patient's mandible 88 relative to the patient's maxilla 90. In a stage or step 100, the position of one of brackets 12 and 14, in this case lower bracket 14, is relatively adjusted to an initial position. This may be done with the initial position adjustment mechanism 50, as discussed above. Stage or step 100 may be performed or carried out before or after protruder 10 is in place in the patient's mouth. As discussed, the initial position may comprise a rest position where the mandible is protruded somewhat relative to a fully retruded position. In some embodiments, the initial position may be a comfortable neutral position for the patient. For example, in some embodiments, step 100 can comprise adjusting the relative position of one of an upper mounting bracket 12 having an upper dental appliance 18, and a lower mounting bracket 14 having a lower dental appliance 20. For example, in the embodiment shown above, the relative position of lower mounting bracket 14 can be adjusted (independently of motor 16) by rotating screw 54 (e.g., via knob 56).

In a stage or step 102 (shown in FIG. 12), the other of brackets 12 and 14, in this case bracket 12, is relatively displaced with drive motor 16 (e.g., as in FIG. 6A) to cause relative displacement between appliances 18 and 20, and to displace (e.g., protrude or retrace), the patient's mandible 88. Step 102 may be accomplished as part of a sleep titration carried out to determine a mandibular protrusion effective in treating obstructive sleep apnea. The effective mandibular protrusion may be determined from a relative position indicator of appliances 18, 20, as discussed above. In a further stage or step, a mandibular protrusion oral appliance, such as a retainer (not shown), may be constructed, adjusted, and/or calibrated for the patient based on the results of the sleep titration. For example, in some embodiments, step 102 can comprise relatively displacing with a drive motor 16 the other of upper mounting bracket 12 and lower mounting bracket 12 when a patient's upper teeth are disposed in (or otherwise coupled to) upper dental appliance 18 and patient's lower teeth are disposed in (or otherwise coupled to) lower dental appliance 20 to cause relative displacement of upper dental appliance 12 and lower dental appliance 14 and displace the patient's mandible relative to the patient's maxilla. For example, in the embodiment shown, motor 16 can be activated to displace upper mounting bracket 12 relative to housing 48 such that lower mounting bracket 14 and lower dental appliance 20, and a patient's mandible, are displaced relative to the patient's maxilla. For example, relatively displacing the other of upper mounting bracket 12

and lower mounting bracket 14 can protrude the patient's mandible relative to the patient's maxilla.

In some embodiments, relatively displacing is repeated while the patient's breathing is monitored and/or may be performed responsive to detection of an interruption in the patient's breathing. As also described in more detail below, some embodiments of the present methods further comprise: determining an optimal mandibular displacement for the patient at which the patient experiences less than a predetermined maximum number of respiratory disturbances in a period of time. For example, in some embodiments, the maximum number of respiratory disturbances corresponds to a respiratory disturbance index (RDI) (e.g., the predetermined maximum number of respiratory disturbances can correspond to an RDI of 10 per hour and/or an RDI that is less than a baseline RDI for the patient) or apnea-hypopnea index (AHI) (e.g., the predetermined maximum number of apneas and hypopneas can correspond to an AHI of 10 per hour and/or an AHI that is less than a baseline AHI for the patient). In some embodiments, the period of time is 10 minutes. In some embodiments, the predetermined number of respiratory disturbances corresponds to no snoring and/or no inspiratory flow limitation (e.g., during rapid eye movement (REM) sleep) and/or is measured when the patient is supine). In some embodiments, the optimal mandibular protrusion is determined from a relative position indicator that indicates relative position of lower dental appliance 14 and upper dental appliance 12. The protruder 10 may be used by a physician or other user to determine an optimal mandibular displacement (e.g., from the patient's natural or resting mandibular position), such that some embodiments of the present methods comprise: communicating the optimal mandibular displacement for the patient to an entity (e.g., a dentist) for construction of a mandibular protrusion oral appliance for the patient.

Some embodiments of the present methods comprise: providing a mandibular protruder 10 (e.g., any of the present embodiments of protruder 10, such as one comprising: an upper mounting bracket 12 having an upper dental appliance 18; a lower mounting bracket 14 having a lower dental appliance 20; a rail system 22 coupling upper mounting bracket 12 to lower mounting bracket 14 such that relative displacement of lower mounting bracket 14 and upper mounting bracket 12 is constrained to linear motion in an anterior-posterior direction; a drive motor 16 configured to effect relative displacement of lower mounting bracket 12 and upper mounting bracket 14; and an initial position adjustment mechanism 50 configured to be actuated to adjust the relative position of lower mounting bracket 14 and upper mounting bracket 12 independently of drive motor 16); actuating initial position adjustment mechanism 50 to adjust the relative position of upper mounting bracket 12 and lower mounting bracket 14; and relatively displacing with drive motor 16 upper mounting bracket 12 and lower mounting bracket 14 when a patient's upper teeth are coupled to (e.g., disposed in) upper dental appliance 18 and patient's lower teeth are coupled to (e.g., disposed in) lower dental appliance 20 to cause relative displacement between upper dental appliance 12 and lower dental appliance 20 and displace the patient's mandible relative to the patient's maxilla.

For example, an overview of an exemplary use of the present protruders (e.g., 10) and/or systems (e.g., as shown in FIG. 11) may go as follows. A dentist or physician may register numerical values, for example on scale 32, corresponding to the fully retruded and fully protruded position of the mandible of a patient. The most convenient zero value of

the scale may occur when the upper and lower incisors are positioned opposite each other, i.e. “end-to-end” position of the mandible **88** relative to the maxilla **90**. With appliances **18** and **20** positioned on the teeth and secured by for example impression material, the dentist may record the reading on scale **32** at the fully retruded position and fully protruded position. These values and appliances **18**, **20** may be given to a technologist who then enters the values into a controlling computer (workstation **92**). Workstation **92** has a software component that allows for the technician to regulate the device. The software in the computer is configured to accept the fully retruded, fully protruded, and “rest” scale readings, and to calculate the position of mandible **88** with these values. Appliances **18** and **20** are then attached to device **19**, and adjustment mechanism **52** of device **19** can be adjusted to the determined rest position or a nominal rest position for comfort (for example fully retruded plus a fixed number of millimeters, e.g., 1, 2, 3, 4, etc. mm). A study (e.g., sleep titration) can be performed (e.g., by a technician) to determine an optimal mandibular displacement for the patient (e.g., a mandibular displacement in which the patient experiences the fewest number of respiratory disturbances) by inputting a command at workstation **92** each time the technician decides or desires to relatively displace (e.g., by an incremental displacement) the patient’s mandible relative to the patient’s maxilla with drive motor **16** (e.g., while the patient is monitored via PSG device **96**). The optimal mandibular displacement (e.g., the target therapeutic distance) such as, for example, relative to zero, can be noted by the technologist at the end of the study and transmitted with appliances **18** and **20** back to the dentist. Optionally, the appliances **18** and **20** can be clipped together following the completion of the study in the position of the optimal mandibular displacement and provided directly to the patient for nightly therapeutic use.

In a further example, the patient first visits the dentist or other healthcare professional to obtain disposable trays **58** and **60**. Some embodiments of the present methods comprise fitting the patient with small, medium, or large trays. Some embodiments comprise filling trays **58** and **60** with Blue-Mousse (Parkell Dental, U.S.A.), boil-and-bite inserts **62**, hardening agent, thermoplastic impression material, and/or the like; inserting top tray **58** into the patient’s mouth, and/or inserting bottom tray **60** into the patient’s mouth (e.g., while rail system **22** is engaged or coupled upper mounting bracket **12** to lower mounting bracket **14**). The patient can be asked to bite down, such as to imprint the material and/or permit the material to harden or quick set. The patient can be asked to move the jaw to a fully retruded position of the patient’s mandible. Some embodiments comprise reading scale **32** (shown in FIG. 7) on top of upper bracket **12** to determine and/or registering (e.g., recording) a relative position value corresponding to the fully retruded position. The patient can be asked to move the jaw to a fully protruded position. Some embodiments comprise reading scale **32** to determine and/or registering a relative position value corresponding to the fully protruded position of the patient mandible. The patient can be asked to move the jaw to a rest position. Some embodiments comprise reading scale **32** to determine and/or registering a relative position value corresponding to the rest position of the patient’s mandible. Some embodiments comprise removing tray **58** and/or **60**. For example, if trays **58** and **60** are individually removed, bottom tray **60** may be removed first. Some embodiments comprise communicating or transferring the scale readings (e.g., retruded, protruded, rest) and/or trays **58** and **60** to another entity (e.g., sleep technician). In some embodiments (e.g., embodiments for

prolonged therapeutic use), the dental impression material is configured to be durable such that the dental impression material will substantially hold its shape for use up to 1, 2, 3, 6, and/or 12 months. In such embodiments, the dental impression material may be molded to a user’s teeth, removed from the patient, and cured or otherwise hardened (e.g., with heat, ultraviolet light, etc.)

Some embodiments of the present methods comprise receiving (e.g., from a dentist) trays **58** and **60** for a patient. Some embodiments comprise coupling (e.g., via rail system **22**) upper tray **58** and lower tray **60**; coupling upper tray **58** to device **19** (e.g., to motor **16**) via connector **46** (e.g., in a fully retraced position flush to housing **48** of device **19**); and/or coupling lower tray **60** to device **19** (e.g., to adjustment mechanism **50**) via connector **52**. Some embodiments comprise adjusting connector **52** (e.g., via adjustment mechanism **50**) to ensure that pointer **34** reads at the reference position of scale **32**. In some embodiments, the reference position is the fully retruded position. In other embodiments, the reference position is fully retruded plus a fixed and repeatable nominal amount, such as, for example, equal to, less than, or between, any of: 1, 2, 3, 4, or 5 mm. The additional adjustment may be chosen to provide patient comfort as the patient may not be comfortable in the fully retruded position. Some embodiments comprise storing the retruded, protruded, and rest scale readings for the patient in the computer workstation **92** (e.g. in a storage device of workstation **92**).

Some embodiments comprise inserting trays **58** and **60** into the patient’s mouth (e.g., together). Some embodiments comprise performing a sleep titration test on the patient. In the embodiment shown, controller **94** may be controlled by workstation **92** to provide control of protruder **10** (e.g., to control relative position of upper mounting bracket **12** and lower mounting bracket **14**). For example, in some embodiments, controller **94** is configured to transmit signals to the drive motor to cause the drive motor to effect relative displacement of the lower mounting bracket and the upper mounting bracket (e.g., to activate the drive motor to displace the upper bracket relative to the housing such that the lower mounting bracket and the patient’s mandible are displaced relative to the patient’s maxilla). In some embodiments controller **94** is also configured to sense the relative position of the lower mounting bracket and the upper mounting bracket, and to transmit (e.g., to workstation) and/or record one or more signals indicative of the position of the lower mounting bracket relative to the upper mounting bracket. In other embodiments, controller **94** comprises a user-input device to permit a user to adjust the relative displacement of upper dental appliance **18** and lower dental appliance **20** by inputting a command directly to controller **92**.

In some embodiments, controller **94** is integral with workstation **92**, and/or workstation **92** is configured to control protruder **10** directly. In some embodiments, controller **94** is configured to power protruder **10** (e.g., controller **94** can include a power source such as one or more batteries and/or a medical-grade alternating current (AC) power source). Additionally, controller **94** and/or workstation **92** may be coupled to a polysomnogram **96** (PSG), and/or may be configured to provide or send input signals to track protruder **10** status (e.g., relative position of upper and lower mounting brackets **12** and **14** or dental appliances **18** and **20**).

In the present embodiments, protruder **10** may be referred to as a remote-control mandibular protruder (RCMP) in which the relative displacement during use (e.g., displace-

ment that is effected by the drive motor, as opposed initial adjustments effected by the initial position adjustment mechanism) is actuated or controlled by a motor or other actuator instead of by physical actuation of the dental appliances or mounting brackets by a user. For example, in the embodiments shown, the motor is activated or controlled by a control signal or by application of a voltage to the motor. In some embodiments, the RCMP (protruder 10) may allow for a level 1 sleep titration with an oral appliance where the patient will not be disturbed or awakened. Some embodiments comprise: remotely adjusting protruder 10 while monitoring and/or responsive to the PSG, such as, for example, to determine optimal settings for the protruder (e.g., similar in some respects to a level 1 CPAP). This may therefore allow a sleep physician to diagnose and/or recommend oral appliances, such as, for example, for patients who do not respond to or do not use a CPAP (e.g., upon CPAP non-compliance).

Referring now to FIG. 19A, example operations for identifying a candidate for oral appliance therapy according to one implementation are shown. Patients can be labeled as favorable candidates for oral appliance therapy if the majority of respiratory disturbances such as apneas, hyponeas, oxygen desaturations, etc., for example, are eliminated. At 1902A, data from a patient sleeping with a dental appliance is received. For example, the data is collected during an OSA titration study such as an oral appliance titration study. The collected data optionally includes data from the patient in all sleeping positions (e.g., supine, lateral, etc.) and all stages of sleep (e.g., REM stages and one or more non-REM stages). In some implementations, the dental appliance can be the mandibular protruder 10 or the remote-control mandibular protruder discussed above. Predictive criteria for determining whether a patient is a favorable candidate for oral appliance therapy can optionally prioritize the use of data collected during REM sleep stages over data collected during one or more non-REM sleep stages. Optionally, the predictive criteria can use only data collected during REM sleep stages. In this implementation, data is collected during REM sleep stages and one or more non-REM sleep stages but only data collected during REM sleep stages is used for the predictive criteria. Thus, at 1904A, at least a portion of the data associated with a period of REM sleep is identified.

Additionally, in some embodiments, the predictive criteria can use a portion of data associated with a period of REM sleep, where the period of REM sleep is greater than or equal to a predetermined length of time. For example, the predictive criteria can use a portion of data associated with a period of REM sleep having a minimum length of 5 minutes, for example. In some implementations, the period of REM sleep can be a continuous, uninterrupted period of REM sleep. Alternatively, the period of REM sleep can be a plurality of fragmented periods of REM sleep that, in the aggregate, are greater than or equal to the predetermined length of time. At 1906A, a number of respiratory disturbances in the portion of data associated with REM sleep are identified. The respiratory disturbances can include, but are not limited to, apneas, hyponeas, oxygen desaturations, etc. The predictive criteria can use a fixed frequency of respiratory disturbances to determine whether the patient is a favorable candidate for oral appliance therapy. For example, if during the portion of data associated with REM sleep, the patient experiences respiratory disturbances at a frequency (e.g., respiratory disturbances per unit time) less than a fixed frequency, then the patient is determined to be a favorable candidate. If, however, during the portion of data associated with REM sleep, the patient experiences respiratory disturbances at a

frequency greater than the fixed frequency, then the patient is determined to be an unfavorable candidate. For example, the fixed frequency can optionally be 1 respiratory disturbance per 5 minute period of REM sleep. Accordingly, at 1908A, a determination can be made as to whether the patient is a favorable candidate for oral appliance therapy.

Referring now to FIG. 19C, example operations for identifying a candidate for oral appliance therapy according to another implementation are shown. Similarly to above, at 1912, data from a patient sleeping with a dental appliance is received. For example, the data is collected during an OSA titration study such as an oral appliance titration study. The collected data optionally includes data from the patient in all sleeping positions (e.g., supine, lateral, etc.) and all stages of sleep (e.g., REM stages and one or more non-REM stages). In some implementations, the dental appliance can be the mandibular protruder 10 or the remote-control mandibular protruder discussed above. Predictive criteria for determining whether a patient is a favorable candidate for oral appliance therapy can optionally prioritize the use of data collected during REM sleep stages over data collected during one or more non-REM sleep stages. Optionally, the predictive criteria can use only data collected during REM sleep stages. Additionally, the predictive criteria can prioritize the use of data associated with REM sleep in a supine position over data collected during REM sleep in a lateral decubitus position. For example, at 1914, at least a portion of the data associated with a period of REM sleep in the supine position is identified.

The predictive criteria can also use a portion of data associated with a period of REM sleep in the supine position, where the period of REM sleep in the supine position is greater than or equal to a predetermined length of time. For example, the predictive criteria can use a portion of data associated with a period of REM sleep in the supine position having a minimum length of 5 minutes, for example. In some implementations, the period of REM sleep in the supine position can be a continuous, uninterrupted period of REM sleep. Alternatively, the period of REM sleep in the supine position can be a plurality of fragmented periods of REM sleep in the supine position that, in the aggregate, are greater than or equal to the predetermined length of time. At 1916, a number of respiratory disturbances in the portion of data associated with a period of REM sleep in the supine position are identified. The respiratory disturbances can include, but are not limited to, apneas, hyponeas, oxygen desaturations, etc. The predictive criteria can use a fixed frequency of respiratory disturbances to determine whether the patient is a favorable candidate for oral appliance therapy. For example, if during the portion of data associated with a period of REM sleep in the supine position, the patient experiences respiratory disturbances at a frequency (e.g., respiratory disturbances per unit time) less than a fixed frequency, then the patient is determined to be a favorable candidate at 1918. For example, the fixed frequency can optionally be 1 respiratory disturbance per 5 minute period of REM sleep. Thus, at 1920, the predictive criteria reveal a predicted success when the frequency of respiratory disturbances is less than or equal to the fixed frequency.

If, however, during the portion of data associated with REM sleep in the supine position, the patient experiences respiratory disturbances at a frequency greater than the fixed frequency at 1918, a determination is made as to whether there is additional data associated with REM sleep in the supine position is available at 1922. According to some implementations, when there are a plurality of portions of data associated with REM sleep in the supine position, the

portions of data associated with periods of REM sleep in the supine position corresponding to smaller amounts of mandibular protrusion are identified and analyzed before the portions of data associated with periods of REM sleep in the supine position corresponding to greater amounts of mandibular protrusion. Thus, if additional data associated with a period of REM sleep in the supine position is available (e.g., data associated with a period of REM sleep in the supine position having a length greater than a predetermined period of time such as 5 minutes, for example), then steps **1914-1918** are repeated for each subsequent portion of data.

If, however, additional data associated with a period of REM sleep in the supine position is not available at **1922**, a determination is made as to whether the patient is a side sleeper at **1924**. As discussed above, the predictive criteria can prioritize the use of data associated with a period of REM sleep in the supine position over data associated with a period of REM sleep in the lateral decubitus position. Evidence that the patient is a side sleeper can be obtained from a patient questionnaire, behavior during the sleep study or from a previous sleep study. In some embodiments, evidence of side sleeping is obtained from an previous sleep study that was conducted in the patient's home or similar environment. To be considered a side sleeper according to implementations discussed herein, the patient should sleep a substantial portion of the night in the lateral position. For example, the patient should sleep the majority of the night (i.e., at least 50%) in the lateral decubitus position. In some implementations, data associated with a period of REM sleep in the lateral position can be used if data associated with a period of REM sleep in the supine position is not available when the patient is a side sleeper. For example, data associated with a period of REM sleep in the lateral position can optionally be used if data associated with a period of REM sleep in the supine position is not available when the patient is a side sleeper, where the period of REM sleep is at least 5 minutes of either continuous, uninterrupted or fragmented REM sleep.

At **1932**, if the patient is a side sleeper, at least a portion of the data associated with a period of REM sleep in the lateral position is identified. The predictive criteria can use a portion of data associated with a period of REM sleep in the lateral position, where the period of REM sleep in the lateral position is greater than or equal to a predetermined length of time. For example, the predictive criteria can use a portion of data associated with a period of REM sleep in the lateral position having a minimum length of 5 minutes, for example. In some implementations, the period of REM sleep in the lateral position can be a continuous, uninterrupted period of REM sleep. Alternatively, the period of REM sleep in the lateral position can be a plurality of fragmented periods of REM sleep in the lateral position that, in the aggregate, are greater than or equal to the predetermined length of time. At **1934**, a number of respiratory disturbances in the portion of data associated with a period of REM sleep in the lateral position are identified. The respiratory disturbances can include, but are not limited to, apneas, hyponeas, oxygen desaturations, etc. The predictive criteria can use a fixed frequency of respiratory disturbances to determine whether the patient is a favorable candidate for oral appliance therapy. For example, if during the portion of data associated with a period of REM sleep in the lateral position, the patient experiences respiratory disturbances at a frequency (e.g., respiratory disturbances per unit time) less than a fixed frequency, then the patient is determined to be a favorable candidate at **1936**. For example, the fixed frequency can optionally be 1 respiratory disturbance per 5

minute period of REM sleep. Thus, at **1920**, the predictive criteria reveal a predicted success when the frequency of respiratory disturbances is less than or equal to the fixed frequency.

If, however, during the portion of data associated with REM sleep in the lateral position, the patient experiences respiratory disturbances at a frequency greater than the fixed frequency at **1936**, a determination is made as to whether there is additional data associated with REM sleep in the lateral position is available at **1938**. According to some implementations, when there are a plurality of portions of data associated with REM sleep in the lateral position, the portions of data associated with periods of REM sleep in the lateral position corresponding to smaller amounts of mandibular protrusion are identified and analyzed before the portions of data associated with periods of REM sleep in the lateral position corresponding to greater amounts of mandibular protrusion. Thus, if additional data associated with a period of REM sleep in the lateral position is available (e.g., data associated with a period of REM sleep in the lateral position having a length greater than a predetermined period of time such as 5 minutes, for example), then steps **1932-1936** are repeated for each subsequent portion of data.

If the patient is not determined to be a side sleeper at **1924** or additional data associated with a period of REM sleep in the lateral position is not available at **1938**, a determination is made as to whether data includes data collected for a predetermined titration range at **1926**. In some implementations, the predetermined titration range includes a maximum protrusion of the mandibular protruder or other titration appliance. Alternatively or additionally, the predetermined titration range includes a range previously specified (i.e., a range specified by the dentist), a maximum voluntary protrusion range of a patient or some other maximum limit. The predetermined titration range can optionally include a maximum protrusion ± 1.0 mm or \pm a percentage, such as $\pm 10\%$. Optionally, the percentage can be a percentage of the protrusive range. In these implementations, the determination requires that the data be collected at the maximum protrusion. If the data includes data collected for the predetermined titration range, the patient is considered an unfavorable candidate for oral appliance therapy. Thus, at **1928**, the predictive criteria reveal a predicted failure. If the data does not include data collected for the predetermined titration range, the data is considered inconclusive at **1930**.

Optionally, if the predictive criteria reveal a predicted success at **1920**, an effective protrusion distance for oral appliance therapy can be determined. As discussed above, when there are a plurality of portions of data associated with REM sleep in the supine position, the portions of data associated with periods of REM sleep in the supine position corresponding to smaller amounts of mandibular protrusion are identified and analyzed before the portions of data associated with periods of REM sleep in the supine position corresponding to greater amounts of mandibular protrusion. The minimum effective amount of mandibular protrusion, therefore, is an amount of mandibular protrusion corresponding to the portion of data associated with the period of REM sleep in the supine position with the smallest amount of mandibular protrusion. This minimum effective amount of mandibular protrusion can optionally be provided as a recommended setting for the oral appliance for oral appliance therapy. In the event that a plurality of portions of data associated with REM sleep in the lateral position are used by the predictive criteria, the portions of data associated with periods of REM sleep in the lateral position corresponding

to smaller amounts of mandibular protrusion are identified and analyzed before the portions of data associated with periods of REM sleep in the lateral position corresponding to greater amounts of mandibular protrusion. The effective amount of mandibular protrusion, therefore, is an amount of mandibular protrusion corresponding to the portion of data associated with the period of REM sleep in the lateral position with the smallest amount of mandibular protrusion. This smallest amount of mandibular protrusion can optionally be provided as a recommended setting for the oral appliance for oral appliance therapy.

Referring now to FIG. 19B, example operations for identifying a candidate for oral appliance therapy according to yet another implementation are shown. In this implementation, example operations for identifying a patient having mild to moderate sleep apnea as a candidate for oral appliance therapy are shown. In some implementations, a patient with mild to moderate sleep apnea can have a respiratory disturbance index less than or equal to 30, for example. Unlike the operations discussed with regard to FIG. 19C, the predictive criteria can use data associated with periods of REM sleep in either the supine or the lateral position regardless of whether the patient is a side sleeper. For example, at 1902B, data from a patient sleeping with a dental appliance is received. For example, the data is collected during an OSA titration study such as an oral appliance titration study. The collected data optionally includes data from the patient in all sleeping positions (e.g., supine, lateral, etc.) and all stages of sleep (e.g., REM stages and one or more non-REM stages). In some implementations, the dental appliance can be the mandibular protruder 10 or the remote-control mandibular protruder discussed above. Predictive criteria for determining whether a patient is a favorable candidate for oral appliance therapy can optionally prioritize the use of data collected during REM sleep stages over data collected during one or more non-REM sleep stages. Optionally, the predictive criteria can use only data collected during REM sleep stages. Thus, at 1904B, at least a portion of the data associated with a period of REM sleep in the supine or the lateral position is identified.

Additionally, in some embodiments, the predictive criteria can use a portion of data associated with a period of REM sleep in the supine or the lateral position, where the period of REM sleep in the supine or the lateral position is greater than or equal to a predetermined length of time. For example, the predictive criteria can use a portion of data associated with a period of REM sleep in the supine or the lateral position having a minimum length of 5 minutes, for example. In some implementations, the period of REM sleep can be a continuous, uninterrupted period of REM sleep. Alternatively, the period of REM sleep can be a plurality of fragmented periods of REM sleep that, in the aggregate, are greater than or equal to the predetermined length of time. At 1906B, a number of respiratory disturbances in the portion of data associated with REM sleep in the supine or the lateral position are identified. The respiratory disturbances can include, but are not limited to, apneas, hyponeas, oxygen desaturations, etc. The predictive criteria can use a fixed frequency of respiratory disturbances to determine whether the patient is a favorable candidate for oral appliance therapy. For example, if during the portion of data associated with REM sleep in the supine or the lateral position, the patient experiences respiratory disturbances at a frequency (e.g., respiratory disturbances per unit time) less than a fixed frequency, then the patient is determined to be a favorable candidate. If, however, during the portion of data associated with REM sleep in the supine or the lateral position, the

patient experiences respiratory disturbances at a frequency greater than the fixed frequency, then the patient is determined to be an unfavorable candidate. For example, the fixed frequency can optionally be 1 respiratory disturbance per 5 minute period of REM sleep in the supine or the lateral position. Accordingly, at 1908B, a determination can be made as to whether the patient is a favorable candidate for oral appliance therapy.

In addition to providing predictive criteria to determine whether a patient is a favorable candidate for an oral appliance, and optionally providing the effective protrusion distance (e.g., a target therapeutic distance), it is also possible to provide a graphical display of the results of an obstructive sleep apnea titration study. For example, the graphical display can be a report summarizing the physiologic signals collected from the polysomnogram (PSG) and the protrusion data collected from the titration system. In some implementations, the data included in the graphical display can include sleep stages (e.g., REM and one or more non-REM sleep stages), counts of respiratory events (e.g., apneas, hyponeas, oxygen desaturations, etc.), sleep positions (e.g., supine, lateral, etc.), oximetry levels and amounts of mandibular protrusion. Optionally, the data included in the graphical display can include only information used in the predictive criteria discussed above (i.e., data associated with REM sleep). The data included in the graphical display can also include at least two of sleep stages, counts of respiratory events, sleep positions, oximetry levels and amounts of mandibular protrusion. Alternatively or additionally, the graphical display can include data for a plurality of steps of the titration study such that an amount of mandibular protrusion is displayed in relation to at least one of a sleep stage, a count of respiratory events, a sleep position and an oximetry level at each step of the titration study. The amount of mandibular protrusion at each step of the titration study can be created automatically by the PSG and/or titration system, manually by the operator, or a combination of both. In some implementations, the graphical display can be a chart displaying the results of the titration study. Alternatively, in other implementations, the graphical display can be a hypnogram displaying the results of the titration study.

In some implementations, an amount of mandibular protrusion at each step of the titration study can be displayed in relation to one or more of the time at each step of the titration study, sleep stage, sleep position, count of respiratory events, oximetry levels, etc. Referring now to FIG. 20, an example chart for displaying results of an obstructive sleep apnea titration study is shown. As shown in FIG. 20, the amount of mandibular protrusion (i.e., Treatment Level) at each step in the titration study occupies a column of the chart. Additionally, other data associated with each step of the titration study occupies additional columns in the chart such that the data associated with each step of the titration study occupies a row in the chart. For example, the chart includes data for the time in REM sleep (TIME REM), the time in REM sleep in the supine position (TIME REM Supine), the time in REM sleep in the lateral position (TIME REM lateral), total respiratory events during REM sleep in the supine position (Events Supine), total respiratory events during REM sleep in the lateral position (Events Lateral) and respiratory event data (e.g., obstructive apnea count, central apnea count, hyponea count, total apnea and hyponea count (A+H Total), apnea-hyponea index (AHI), respiratory effort related arousal (RERA), total respiratory event count and respiratory disturbance index (RDI). It should be understood that the amount of mandibular protrusion and other

data associated with each step of the titration study can alternatively occupy rows in a chart such that the data associated with each step of the titration study occupies a column in the chart.

Optionally, a portion of the graphical display can be highlighted. For example, a portion of the chart including data associated with a period of REM sleep can be highlighted. As discussed above, the predictive criteria can use data associated with a period of REM sleep in the supine position (or in some cases the lateral position) greater than or equal to a predetermined length of time (e.g., 5 minutes). In some implementations, one or more portions of the chart including data associated with periods of REM sleep greater than or equal to the predetermined length of time can be highlighted. Alternatively or additionally, one or more portions of the chart including data associated with periods of REM sleep greater than or equal to the predetermined length of time, as well as having a frequency of respiratory events less than or equal to a fixed frequency (e.g., 1 event/5 minute period), can be highlighted. For example, as shown in FIG. 20, portions of the chart **2001** are highlighted. The portions of the chart **2001** are segments of REM sleep in the supine position greater than 5 minutes along with corresponding counts of respiratory events. In particular, the portions of the chart **2001** are segments at 14.2 mm of mandibular protrusion with 0 respiratory events and 14.4 mm of protrusion with 4 respiratory events. Although FIG. 20 illustrates highlighting the amount of mandibular protrusion and the count of respiratory events, it should be understood that any data associated with the amount of mandibular protrusion can optionally be highlighted.

Referring now to FIG. 21, an example hypnogram for displaying results of an obstructive sleep apnea titration study is shown. The hypnogram graphically displays the amount of mandibular position in temporal relation to sleep stages (e.g., REM and one or more non-REM stages), respiratory events (e.g., apneas, hyponeas, oxygen desaturations, etc.), body positions (e.g., supine, lateral, etc.) and oximetry levels. Similarly to the chart in FIG. 20, a portion of the graphical display can optionally be highlighted. For example, a portion of the hypnogram including data associated with a period of REM sleep can be highlighted. As discussed above, the predictive criteria can use data associated with a period of REM sleep in the supine position (or in some cases the lateral position) greater than or equal to a predetermined length of time (e.g., 5 minutes). In some implementations, one or more portions of the hypnogram including data associated with periods of REM sleep greater than or equal to the predetermined length of time can be highlighted. Alternatively or additionally, one or more portions of the hypnogram including data associated with periods of REM sleep greater than or equal to the predetermined length of time, as well as having a frequency of respiratory events less than or equal to a fixed frequency (e.g., 1 event/5 minute period), can be highlighted. For example, as shown in FIG. 21, portions of the hypnogram **2101** are highlighted. The portions of the hypnogram **2101** are segments of REM sleep in the supine position greater than 5 minutes along with corresponding counts of respiratory events, sleep stages, oximetry levels and sleep positions.

It should be appreciated that the logical operations described herein with respect to the various figures may be implemented (1) as a sequence of computer implemented acts or program modules (i.e., software such as (a) an automated titration study scoring software, (b) the polysomnogram software, (c) the titration system software, (d) a

third party software, or (e) any other software) running on a computing device, (2) as interconnected machine logic circuits or circuit modules (i.e., hardware) within the computing device and/or (3) a combination of software and hardware of the computing device. Thus, the logical operations discussed herein are not limited to any specific combination of hardware and software. The implementation is a matter of choice dependent on the performance and other requirements of the computing device. Accordingly, the logical operations described herein are referred to variously as operations, structural devices, acts, or modules. These operations, structural devices, acts and modules may be implemented in software, in firmware, in special purpose digital logic, and any combination thereof. It should also be appreciated that more or fewer operations may be performed than shown in the figures and described herein. These operations may also be performed in a different order than those described herein.

When the logical operations described herein are implemented in software, the process may execute on any type of computing architecture or platform. For example, referring to FIG. 22, an example computing device upon which embodiments of the invention may be implemented is illustrated. In particular, the controller **94**, the PSG device **96** and/or the workstation **92** discussed above include a computing device, such as computing device **2200** shown in FIG. 22. The computing device **2200** may include a bus or other communication mechanism for communicating information among various components of the computing device **2200**. In its most basic configuration, computing device **2200** typically includes at least one processing unit **2206** and system memory **2204**. Depending on the exact configuration and type of computing device, system memory **2204** may be volatile (such as random access memory (RAM)), non-volatile (such as read-only memory (ROM), flash memory, etc.), or some combination of the two. This most basic configuration is illustrated in FIG. 22 by dashed line **2202**. The processing unit **2206** may be a standard programmable processor that performs arithmetic and logic operations necessary for operation of the computing device **2200**.

Computing device **2200** may have additional features/functionality. For example, computing device **2200** may include additional storage such as removable storage **2208** and non-removable storage **2210** including, but not limited to, magnetic or optical disks or tapes. Computing device **2200** may also contain network connection(s) **2216** that allow the device to communicate with other devices. Computing device **2200** may also have input device(s) **2214** such as a keyboard, mouse, touch screen, etc. Output device(s) **2212** such as a display, speakers, printer, etc. may also be included. The additional devices may be connected to the bus in order to facilitate communication of data among the components of the computing device **2200**. All these devices are well known in the art and need not be discussed at length here.

The processing unit **2206** may be configured to execute program code encoded in tangible, computer-readable media (or non-transitory computer-readable media). Computer-readable media refers to any media that is capable of providing data that causes the computing device **2200** (i.e., a machine) to operate in a particular fashion. Various computer-readable media may be utilized to provide instructions to the processing unit **2206** for execution. Common forms of computer-readable media include, for example, magnetic media, optical media, physical media, memory chips or cartridges, a carrier wave, or any other medium from which a computer can read. Example tangible, computer-readable

media may include, but is not limited to, volatile media, non-volatile media and transmission media. Volatile and non-volatile media may be implemented in any method or technology for storage of information such as computer readable instructions, data structures, program modules or other data and common forms are discussed in detail below. Transmission media may include coaxial cables, copper wires and/or fiber optic cables, as well as acoustic or light waves, such as those generated during radio-wave and infra-red data communication.

In an example implementation, the processing unit **2206** may execute program code stored in the system memory **2204**. For example, the bus may carry data to the system memory **2204**, from which the processing unit **2206** receives and executes instructions. The data received by the system memory **2204** may optionally be stored on the removable storage **2208** or the non-removable storage **2210** before or after execution by the processing unit **2206**.

Computing device **2200** typically includes a variety of computer-readable media. Computer-readable media can be any available media that can be accessed by device **2200** and includes both volatile and non-volatile media, removable and non-removable media. Computer storage media include volatile and non-volatile, and removable and non-removable media implemented in any method or technology for storage of information such as computer readable instructions, data structures, program modules or other data. System memory **2204**, removable storage **2208**, and non-removable storage **2210** are all examples of computer storage media. Computer storage media include, but are not limited to, RAM, ROM, electrically erasable program read-only memory (EEPROM), flash memory or other memory technology, CD-ROM, digital versatile disks (DVD) or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by computing device **2200**. Any such computer storage media may be part of computing device **2200**.

It should be understood that the various techniques described herein may be implemented in connection with hardware or software or, where appropriate, with a combination thereof. Thus, the methods and apparatuses of the presently disclosed subject matter, or certain aspects or portions thereof, may take the form of program code (i.e., instructions) embodied in tangible media, such as floppy diskettes, CD-ROMs, hard drives, or any other machine-readable storage medium wherein, when the program code is loaded into and executed by a machine, such as a computing device, the machine becomes an apparatus for practicing the presently disclosed subject matter. In the case of program code execution on programmable computers, the computing device generally includes a processor, a storage medium readable by the processor (including volatile and non-volatile memory and/or storage elements), at least one input device, and at least one output device. One or more programs may implement or utilize the processes described in connection with the presently disclosed subject matter, e.g., through the use of an application programming interface (API), reusable controls, or the like. Such programs may be implemented in a high level procedural or object-oriented programming language to communicate with a computer system. However, the program(s) can be implemented in assembly or machine language, if desired. In any case, the language may be a compiled or interpreted language and it may be combined with hardware implementations.

Some embodiments of the present methods comprises communicating or transmitting the results of the sleep titration to an entity (e.g., a dentist), such as, for example, in the form of either a scale reading or protrusion amount (e.g., an optimal mandibular displacement), such as, for example, from either max retrusion or distance from when the teeth are end to end. Some embodiments of the present methods comprises receiving and/or accessing the results of the sleep titration (e.g., performed using one or more of the present protruders, positioning devices, and/or apparatuses) from, for example, an entity (e.g., a dentist or physician). Some embodiments comprise producing, prescribing, and/or ordering an oral appliance based on the results (e.g., an oral appliance for the patient with the optimal mandibular displacement). Some embodiments comprise adjusting and/or calibrating an oral appliance (e.g., a commercially-available oral appliance, such as, for example, a MAS appliance available from SomnoMed, Canada, U.S.A., Australia) to have a mandibular displacement corresponding to an optimal mandibular displacement. In some embodiments, trays **58** and **60** may be used in and/or may be used to make or produce the oral appliance. For example, upper and lower trays **58** and **60** can be coupled with a screw, clamp, adhesive, or the like to statically fit together at a specified displacement (e.g., optimal mandibular displacement). After the patient has been given the produced oral appliance, such as a mandibular protrusion retainer, check-ups may be carried out as desired to ensure useful functioning. Some embodiments of the present oral appliances comprise an oral appliance that has been adjusted to cause an optimal mandibular displacement when worn by a patient, the optimal mandibular displacement for the patient having been determined by a sleep titration performed with an embodiment of the present protruders, devices, and/or systems.

In some embodiments, controller **94** may include and/or house batteries sufficient to motorize the protruder **10**, and electronics sufficient to control or send control signals to protruder **10** and/or transmit data (e.g., to workstation **92** or PSG device **96**). Controller **94** may be coupled to (e.g., in electronic communication with) protruder **10** via a cable and may be expected to reside under a pillow or on a night stand during the patient study. Protruder **10** may have a wired or wireless bidirectional connection to a control module (e.g., workstation **92** or other control module) that allows a technician to alter the displacement amounts and regulate device status from another room. Protruder **10** may also have a unidirectional connection to a PSG **96** to permit logging of activity over time and generation of a single inclusive report or data stream (e.g., to workstation **92**), which may include a single or multiple output jack, such as, for example, similar to output jacks on CPAP machines, which will interface with PSG devices **96** to provide data output.

Workstation **92** may include the software component with which a technician interfaces to control and receive status information on protruder **10**. Workstation **92** and/or appropriate software may be configured to communicate with controller **94** either wired or wirelessly to provide or enable bi-directional status and control data. The software may be configured to display status information like force and position, as well as control movement or position of protruder **10** to retract or extend lower appliance **20** and the patient's mandible relative to upper appliance **18** and the patient's maxilla. The software component may comprise an application configured to separately or solely control protruder **10** (as opposed to jointly controlling protruder **10** and PSG device **96**), and may, for example: include the capability to increase or decrease relative displacement of lower

appliance 20 relative to upper appliance 18; set the increments at which to move linear actuator 17 of motor 16; and/or reset protruder 10 (e.g., lower appliance 20) to the rest position. The software may also be configured to include safety features and restrictions on protruder 10, such as, for example, to prevent extending or retracting the jaw beyond pre-set limits and/or to prevent protruder 10 from exerting a force on mandible in excess of a predetermined maximum (e.g., a force equivalent to 2 kilograms).

Coupling components may be achieved through additional unmentioned parts, structures, or configurations that permit the components to be coupled in the manner described. Two components that are coupled may include the two components being integral with one another, if such a configuration would permit the two components to interrelate in the manner claimed. When a first component has or includes a second component, it can include embodiments in which the first and second components are connected together or through other parts. Also, it should be understood that various portions or components of embodiments disclosed herein may be used in other embodiments disclosed herein. For example, the present disclosure includes embodiments of mandibular protruders, mandibular positioning devices that may be suitable for use in embodiments of the present mandibular protruders, and apparatuses that may be suitable for use with embodiments of the present mandibular positioning devices and/or in embodiments of the present mandibular protruders.

In one example, the present disclosure includes various embodiments of a mandibular protruder (e.g., 10) comprising: an upper mounting bracket 12 having an upper dental appliance 18; a lower mounting bracket 14 having a lower dental appliance 20, the lower mounting bracket configured to be coupled to the upper mounting bracket such that relative motion of the lower mounting bracket and the upper mounting bracket is constrained to linear motion in an anterior-posterior direction; a mandibular positioning device 19 configured to be coupled to upper mounting bracket 12 and lower mounting bracket 14, the mandibular positioning device having a drive motor 16 configured to adjust the relative position of lower mounting bracket 14 and upper mounting bracket 12 if the mandibular positioning device is coupled to upper mounting bracket 12 and lower mounting bracket 14; an upper release mechanism configured to release upper dental appliance 18 from mandibular positioning device 19 if mandibular positioning device 19 is coupled to upper mounting bracket 12; and a lower release mechanism configured to release lower dental appliance 20 from mandibular positioning device 19 if mandibular positioning device 19 is coupled to lower mounting bracket 14.

In another example, the present disclosure includes various embodiments of a mandibular protruder (e.g., 10) comprising: an upper mounting bracket 12 having an upper dental appliance 18; a lower mounting bracket 14 having a lower dental appliance 20, the lower mounting bracket configured to be coupled to the upper mounting bracket such that the lower mounting bracket can move linearly relative to the upper mounting bracket; a drive motor 16 coupled to one of upper mounting bracket 12 and lower mounting bracket 14, the drive motor configured to effect relative displacement of lower mounting bracket and the upper mounting bracket; and an initial position adjustment mechanism 50 configured to adjust an initial position of the other of the upper mounting bracket and the lower mounting bracket.

In another example, the present disclosure includes various embodiments of a mandibular positioning device (e.g.,

19) comprising: a drive motor 16 having a connector 46 configured to be coupled to a mounting bracket (e.g., 12 or 14) of a first dental appliance (e.g., 18 or 20); an adjustment mechanism 50 having a connector 52 configured to be coupled to a mounting bracket (e.g., 12 or 14) of a second dental appliance (e.g., 18 or 20); and a housing 48 having a sidewall with at least a first opening and a second opening, the housing coupled to drive motor 16 and the adjustment mechanism 50 such that the housing encloses at least a portion of each of the drive motor and the adjustment mechanism, the drive-motor connector extends out of the housing through the first opening, and the adjustment-mechanism connector extends out of the housing through the second opening. In some embodiments, adjustment mechanism 50 is configured to linearly adjust the position of the adjustment-mechanism connector. In some embodiments, drive motor 16 is configured to linearly move the drive-motor connector in a direction substantially parallel to the direction in which the adjustment mechanism can adjust the adjustment-mechanism connector.

In another example, the present disclosure includes various embodiments of an apparatus for use with a mandibular positioning device (e.g., 19), the apparatus comprising: an upper mounting bracket 12 having an upper dental appliance 14; a lower mounting bracket 14 having a lower dental appliance 20, the lower mounting bracket configured to be coupled to the upper mounting bracket such that relative linear motion of the lower mounting bracket and the upper mounting bracket is permitted; and a relative position indicator for indicating relative position of the lower dental appliance and the upper dental appliance; where the apparatus is configured such that the lower mounting bracket can be coupled to the upper mounting bracket and such that the upper mounting bracket and the lower mounting bracket can be independently coupled to a first connector (e.g., 46) and a second connector (e.g., 52) respectively of a mandibular positioning device.

FIG. 13 depicts a polymeric bag 150 that is configured to fit around device 19 to reduce and/or prevent contamination of device 19 during use. In the embodiment shown, bag 150 has a first end 152 and a second end 154. Second end 154 includes an opening 156 and a flap 158 comprising an (e.g., pressure-sensitive) adhesive 158. Bag 150 is configured to permit device 19 to be inserted through opening 156 such that flap 158 can be folded over to cover opening 156 and adhesive 160 will hold flap 158 over opening 156. First end 152 includes extended portions 162 and 164 configured to permit connectors 46 and 52 to extend out of bag 150 when device 19 is disposed in bag 150 (e.g., during operation of device 19 and/or protruder 10). More particularly, in the embodiment shown, extended portion 162 includes a hole 166 configured to permit connector 46 to extend out of hole 166, and extended portion 164 has a hole 168 configured to permit connectors 52 to extend out of through hole 168. Polymeric bag 150 can comprise, for example, a plastic or other liquid-and/or gas-impermeable material that is configured to reduce contaminate of device 19 and/or protruder 10 generally, such as with body fluids and/or the like. In the embodiment shown, bag 150 is disposable (e.g., after a single use) and is a single-use bag.

Alternatively or additionally, some embodiments can comprise: a polymeric bag (not shown), configured to fit around at least one (e.g., both) of upper dental appliance 18 and lower dental appliance 20, and/or two bags each configured to fit around one of upper dental appliance 18 and lower dental appliance 20. In some embodiments, the polymeric bag is configured to fit between dental impression

material and the at least one of upper dental appliance **18** and lower dental appliance **20**. In some embodiments, a polymeric bag is configured to fit around device **19**. Some embodiments of the present methods comprise disposing a positioning device (e.g., **19**) in a polymeric bag (e.g., **150**) such that a drive-motor connector (e.g., **46**) and/or an adjustment-mechanism connector (e.g., **52**) extend out of the polymeric bag; coupling an upper mounting bracket (e.g., **12**) having an upper dental appliance (e.g., **18**) to one of the drive-motor connector and the adjustment-mechanism connector, and a lower mounting bracket (e.g., **14**) having a lower dental appliance (e.g., **20**) to the other of the drive-motor connector and the adjustment-mechanism connector (e.g., such that the upper mounting bracket and lower mounting bracket are coupled by a rail system (e.g., **22**); and/or actuating the device to displace a patient's mandible relative to the patient's maxilla.

FIGS. **14A** and **14B** depict an alternate embodiment **10A** of the present protruders. FIGS. **14C-14F** depict upper mounting bracket **12a** and lower mounting bracket **14a** of protruder **10a**. Protruder **10a** is substantially similar to protruder **10**, above, except where noted. Components of protruder **10a** are numbered similarly to similar components of protruder **10** (e.g., connector **46a** and connector **46**), and such similarly numbered components are substantially similar, except where otherwise noted. The description of protruder **10a** will therefore focus on the differences between protruder **10a** and protruder **10**. FIG. **14F** depicts a cross-sectional view of alternate housing **48a**.

In the embodiment shown, rail system **22a** (e.g., guides **23a**) is spaced apart from upper dental appliance **18a** and lower dental appliance **20a**. More particularly, at least one of (e.g., both of upper mounting bracket **12a** and lower mounting bracket **14a**) includes an elongated planar portion (e.g., elongated planar portion of upper mounting bracket **12** that extends from upper dental appliance **18a** to the end of bracket **12** that couples to connector **46a**) having a length, and rail system **22a** has a length that is less than (e.g., less than 30, 40, 50, 60, 70, 80, 90 percent of) the length of the elongated planar portion. Additionally, in the embodiment shown, housing **48a** includes a back portion **200** that is openable or removable by way of clips **204** that are configured to extend through openings **208**. Housing **48a** is also configured to include enlarged portions **212** and **214** adjacent to the holes through which connectors **46a** and **52a** extend. In the embodiment shown, enlarged portions **212** and **214** are larger than the respective holes, and are configured to receive a seal between housing **48a** and respective connectors **46a** and **52a**.

In the embodiment shown, one or more (e.g., two) pointers **34a** are each coupled to (e.g., integral with) the top of a guide **23a**, such that, for example, the pointer need not extend beyond or be disposed between the guide **23a** closes to trays **58a** and **60a**, thereby permitting a reduction in the length of rail system **22a**. Additionally, in the embodiment shown, the upwardly extending portion (through which hole **75a** passes) of upper mounting bracket **12a** that is configured to be coupled to connector **46a** has a maximum width that is less than the distance between the inner edges of opposing guides **23a** of rail system **22** (guides **23a** on opposite sides of upper mounting bracket **12a**). Similarly, in the embodiment shown, the downwardly extending portion (through which hole **79a** passes) of lower mounting bracket **14a** that is configured to be coupled to connector **52a** also has a maximum width that is less than the distance between the inner edges of opposing guides **23a** of rail system **22a** (guides **23a** on opposite sides of upper mounting bracket

12a). In contrast, protruder **10**, above, is configured such that the upwardly extending portion (through which hole **75** passes) of upper mounting bracket **12** that is configured to be coupled to connector **46** has a maximum width that is greater than the distance between the inner edges of opposing guides **23** of rail system **22**; and such that the downwardly extending portion (through which hole **79** passes) of lower mounting bracket **14** that is configured to be coupled to connector **52** has a maximum width that is greater than the distance between the inner edges of opposing guides **23** of rail system **22**.

In the embodiment shown, lateral portions **70a** and **72a** of upper dental appliance **18a** (tray **58a**) and lower dental appliance **20a** (tray **60a**) are relatively shorter than lateral portions **70** and **72** of trays **58** and **60**, respectively. More particularly, trays **58a** and **60a** are configured to receive a patient's upper and lower teeth, respectively, such that at least one of lateral portions **70a** and **72a** terminate anterior to (e.g., extend no further back than) one or more of the patient's molars (e.g., third molar, second molar, and/or first molar). In the embodiment shown, device **19a** (e.g., housing **48a**, as shown) comprises one or more (two, as shown) indicators **216** that indicate which side of device **19a** should face upwards during use, and thereby which of connectors **46** and **52** should correspond to upper mounting bracket **12**.

FIG. **14H** illustrates cross-sectional view of a seal **218** suitable for use in some embodiments of the present mandibular protruders (e.g., **10**). In the embodiment shown, housing **48a** (see also FIG. **14G**) is sectioned parallel to the longitudinal axis of connector **46a**, however, seal **218** is also suitable for use around connector **52a**. For example, in the embodiment shown, protruder **10a** comprises a first seal **218** disposed around drive-motor connector **46a** between housing **48a** and drive-motor connector **46a** (as shown, in enlarged portion **212**); and a second seal **218** disposed around adjustment-mechanism connector **52a** between housing **48a** and adjustment-mechanism connector **52** (as shown, in enlarged portion **214**). In the embodiment shown, seal **218** is donut-shaped (such that connector **46** extends through the center opening) and comprises a seal body **222** and a coil spring **226** coupled to seal body **222**. More particularly, seal body **222** comprises an annular opening (e.g., around connector **46a**, as shown) into which coil spring **226** is received. In the embodiment shown, coil spring **226** has an oval-shaped cross-section. Seal **218** may comprise a U-N130 series seal available from BAL SEAL ENGINEERING, U.S.A., and may be referred to by BAL SEAL by part number X572322.

FIGS. **15A-15D** depict various views of an adjustment-mechanism connector or rod **52a** suitable for use in embodiments of the present protruders (e.g., **10a**). Connector **52a** is substantially similar to connector **52**, above, except where noted. The description of connector **52a** will therefore focus on the differences between connector **52a** and connector **52**. Connector **52a** comprises an enlarged portion **258**. Portion **258** has a length that is equal to, between, or less than any 30, 40, 50, 60, 70, 80, 90 percent of the overall length of connector **52a**. In the embodiment shown, enlarged portion **258** has a cross-section that is larger than the cross-section of the relatively smaller portion of connector **52a** that extends out of housing **48a**. Enlarged portion **258** is thus configured to limit the displacement of connector **52a** relative to housing **48a** because enlarged portion **258** is too large to exit housing **48a** during actuation of the adjustment mechanism. In the embodiment shown, connector **52a** includes longitudinal protrusions **55a** that extend the full length of enlarged portion **258**.

FIGS. 16A-16B are cutaway-perspective and side cross-sectional views, respectively, of another embodiment 19b of the present positioning devices. Device 19b is substantially similar to device 19a, above, except where noted. Components of device 19b are numbered similarly to similar components of device 19a (e.g., connector 46b and connector 46a), and such similarly numbered components are substantially similar, except where otherwise noted. The description of device 19b will therefore focus on the differences between device 19b and device 19a. FIG. 16C depicts a cross-sectional view of housing 48b. Housing 48b of device 19b includes a protruded portion 262 that is configured to receive a plug 266 (e.g., a female plug, as shown). Female plug 266 is wired to drive motor 16 such that a male plug (not shown) can be removably coupled to female plug 266 to apply voltage and/or send control signals to drive motor 16 (e.g., from controller 94 and/or workstation 92). Additionally, in the embodiment shown, device 19b includes an enlarged knob 56b that is configured to be turned by hand (e.g., knob 56b has a transverse dimension that is at least twice as large as the diameter of screw 54b).

Referring now to FIGS. 17A-17B, FIG. 17A is a cutaway perspective view of another embodiment 19c of the present positioning devices; and FIG. 17B is a side view of another embodiment of the present protruders 10c that includes positioning device 19c. Device 19c is substantially similar to device 19b, with the exception that plug 266c of device 19c has a circular configuration in which a plurality of pins are arranged in a circular shape.

The various illustrative embodiments of devices, systems, and methods described herein are not intended to be limited to the particular forms disclosed. Rather, they include all modifications and alternatives falling within the scope of the claims.

The claims are not intended to include, and should not be interpreted to include, means-plus- or step-plus-function limitations, unless such a limitation is explicitly recited in a given claim using the phrase(s) "means for" or "step for," respectively.

EXAMPLES

In a clinical study of 67 patients, subjects were labeled a favorable candidate (predicted success) if a minimum of 5 minutes of REM sleep in the supine position was achieved with less than 1 event for every 5 minutes within the REM sleep period. Additionally, for subjects that demonstrated in a baseline study that they spent the majority of the night in the lateral position (e.g., >50%), subjects were labeled a favorable candidate (predicted success) if REM sleep in the supine position was not achieved and a minimum of 5 minutes of REM sleep in the lateral position was achieved with less than 1 event per 5 minutes. Alternatively, subjects were labeled as unfavorable candidates (predicted failures) if more than 1 event was observed for every 5 minutes within the REM period at near maximum protrusion (within 1 mm). Otherwise, subjects were labeled as inconclusive due to inadequate data. The study found that the sensitivity and specificity of the test was 86% and 92%, respectively. Only 9% of patients were found to have inadequate data. In the study, to apply the above criteria, and provide an interpretation of the titration study, the scored data from the polysomnogram was compared and reviewed alongside the corresponding position data from the titration device.

The efficacy of using the output from a technician controlled RCMP titration device to determine the geometry of an oral appliance was determined. The geometry was deter-

mined by selecting the minimal amount of protrusion where the number of events in REM, in either supine or lateral depending on the patient, met the criteria. Testing was performed by a dental investigator and/or one or more sleep physicians as described below on 67 different subjects with symptoms of obstructive sleep apnea.

Each subject received a two night baseline, pre-treatment, respiratory evaluation in the home using a portable sleep monitor. Each subject was then evaluated by the dental co-investigator and fitted with upper and lower dental titration trays filled with the impression material. The dentist measured the maximum retrusion and protrusion values from the scale on the titration trays. On the night of the titration study, the values provided by the dentist, for maximum retrusion and protrusion, were entered into the RCMP titration software. The titration trays were attached to the mandibular positioner and the position of the trays was adjusted by the manually adjustable knob to near full retrusion. The trays were then inserted into the subject's mouth and used for the duration of the titration study. Once the patient was asleep, the technician protruded the mandible step wise at a minimum 0.2 mm per step, using the RCMP titration device, until all evidence of pharyngeal obstruction (apnea or hypopnea) was eliminated in non-REM and REM sleep or until maximum protrusion was reached.

The study was scored by a polysomnographic technologist to identify respiratory disturbances (using 4a scoring rules). The results of the RCMP titration were reviewed without knowing patient specific information or other clinical data related to the subject to make a prospective prediction regarding therapeutic outcome. A strict set of prospectively determined criteria for the prediction were followed. Subjects were labeled a favorable candidate (predicted success) if a minimum of 5 minutes of REM sleep in the supine position was achieved with less than 1 event for every 5 minutes within the REM sleep period. Additionally, for subjects that demonstrated in a baseline study that they spent the majority of the night in the lateral position (e.g., >50%), subjects were labeled a favorable candidate (predicted success) if REM sleep in the supine position was not achieved and a minimum of 5 minutes of REM sleep in the lateral position was achieved with less than 1 event per 5 minutes. Alternatively, subjects were labeled as unfavorable candidates (predicted failures) if more than 1 event was observed for every 5 minutes within the REM period at near maximum protrusion (within 1 mm). Otherwise, subjects were labeled as inconclusive due to inadequate data.

For subjects labeled favorable candidates (predicted success), the protrusive position at which the obstruction was removed (as recorded on the scored PSG data) was recorded by the technician and forwarded to the dental co-investigator. For subjects labeled unfavorable candidates (predicted failure) and inconclusive, a 70 percent of full protrusion was recorded as the sham position for use by the dental co-investigator. The positions, actual and sham, were used to manufacture the subjects' permanent mandibular repositioning appliance (MRA) (e.g., a Somnosed MAS Acrylic oral appliance). The subject and the dental co-investigator were blinded to the results of the RCMP polysomnographic study (i.e., to the prediction of favorable or unfavorable candidate) made by the clinical co-investigator. An outcome, post-treatment, respiratory evaluation during sleep using the same portable monitor used for baseline studies was performed on two nights in the home with the mandibular repositioning appliance (MRA) in place at the target protrusive distance.

Successful treatment with MRA was defined prospectively as achieving a respiratory disturbance index with the appliance set at target protrusion (number of apneas and hypopneas per hour) by the automated analysis on the post treatment portable monitoring test less than 10/hr.

Twenty-five subjects were predicted to be failures with oral appliance therapy and thirty-six were predicted to be therapeutic successes, and six inconclusive. All patients who were predicted successes were therapeutic successes, and 7 of the 25 predicted failures were found to therapeutic successes. Overall the outcome was as follows: sensitivity: 74.4%; specificity: 100%; positive predictive value: 100%; negative predictive value: 62.1%. The positive predictive value at target protrusion was 93.8%. The results demonstrate that the predictive criteria utilizing only REM sleep stages, and prioritizing the use of supine, provides effective method of selecting candidates that will be successful with oral appliance therapy and their target protrusion distance.

Additionally, the same set of data were analyzed by a second strict set of criteria for the prediction. Subjects with a baseline RDI between 10 and 20 hr⁻¹ were labeled a favorable candidate (predicted success) if either a minimum of 5 minutes of REM in the supine position or REM the lateral position was achieved with less than 1 event for every 5 minutes within the REM period. Subjects were labeled as unfavorable candidates (predicted failures) if more than 1 event was observed for every 5 minutes within the REM period at near maximum protrusion (within 1 mm). Otherwise, the subjects were labeled as inconclusive due to inadequate data.

Twenty-nine subjects were predicted to be failures with oral appliance therapy and thirty-two were predicted to be therapeutic successes, and six inconclusive. All patients who were predicted successes were therapeutic successes, and 11 of the 25 predicted failures were found to therapeutic successes. Overall the outcome was as follows: sensitivity: 72%; specificity: 100%; positive predictive value: 100%; negative predictive value: 83.7%. The positive predictive value at target protrusion was 92%. The results demonstrate that the predictive criteria utilizing only REM sleep stages, and treating supine and lateral equivocally for patients with mild-moderate sleep apnea, provides effective method of selecting candidates that will be successful with oral appliance therapy and their target protrusion distance.

Although the subject matter has been described in language specific to structural features and/or methodological acts, it is to be understood that the subject matter defined in the appended claims is not necessarily limited to the specific features or acts described above. Rather, the specific features and acts described above are disclosed as example forms of implementing the claims.

What is claimed:

1. A method for identifying a candidate for oral appliance therapy, comprising:

collecting, using a sleep data collection system, data from a patient while the patient is sleeping with a dental appliance, the data being associated with one or more periods of rapid eye movement (REM) sleep and non-REM sleep;

transmitting the data from the sleep data collection system to a computing device;

identifying, using the computing device, at least a portion of the data from a period of REM sleep;

identifying, using the computing device, a number of respiratory disturbances in the portion of the data from the period of REM sleep; and

prospectively determining whether the patient is a favorable candidate for oral appliance therapy based on the number of respiratory disturbances in the portion of the data from the period of REM sleep,

wherein the determination of whether the patient is a favorable candidate for oral appliance therapy is made by evaluating the number of respiratory disturbances identified in data collected during REM sleep only; wherein a favorable candidate for oral appliance therapy achieves a therapeutic end-point during oral appliance therapy; and

wherein the favorable candidate experiences less than a predetermined maximum number of respiratory disturbances during oral appliance therapy.

2. The method of claim 1, wherein a frequency of respiratory disturbances in the portion of the data from the period of REM sleep is less than or equal to a threshold frequency.

3. The method of claim 2, wherein the threshold frequency is 1 respiratory disturbance per 5 minute period.

4. The method of claim 2, wherein the patient is a favorable candidate for oral appliance therapy when the frequency of respiratory disturbances in the portion of the data from the period of REM sleep is less than or equal to the threshold frequency.

5. The method of claim 4, further comprising determining an effective protrusion distance, the effective protrusion distance being a minimum protrusion distance corresponding to the portion of the data from the period of REM sleep.

6. The method of claim 1, wherein the period of REM sleep is equal to or greater than 5 minutes.

7. The method of claim 6, wherein the period of REM sleep comprises a continuous, uninterrupted period of REM sleep.

8. The method of claim 6, wherein the period of REM sleep comprises a plurality of fragmented periods of REM sleep.

9. The method of claim 1, wherein the data is further associated with one or more periods of sleep in a supine position and a lateral position, the method further comprising:

identifying a portion of data from a period of REM sleep in the supine position;

identifying a number of respiratory disturbances in the portion of the data from the period of REM sleep in the supine position; and

determining whether the patient is a favorable candidate for oral appliance therapy based on the number of respiratory disturbances in the portion of the data from the period of REM sleep in the supine position.

10. The method of claim 9, wherein the period of REM sleep in the supine position is less than 5 minutes, the method further comprising:

identifying a portion of data from a period of REM sleep in the lateral position;

identifying a number of respiratory disturbances in the portion of the data from the period of REM sleep in the lateral position; and

determining whether the patient is a favorable candidate for oral appliance therapy based on the number of respiratory disturbances in the portion of the data from the period of REM sleep in the lateral position.

11. The method of claim 10, wherein a frequency of respiratory disturbances in the portion of the data from the period of REM sleep in the lateral position is less than or equal to a threshold frequency.

12. The method of claim 11, wherein the threshold frequency is 1 respiratory disturbance per 5 minute period.

13. The method of claim 11, wherein the patient is a favorable candidate for oral appliance therapy when the frequency of respiratory disturbances in the portion of the data from the period of REM sleep in the lateral position is less than or equal to the threshold frequency.

14. The method of claim 13, further comprising determining an effective protrusion distance, the effective protrusion distance being a minimum protrusion distance corresponding to the portion of the data from the period of REM sleep in the lateral position.

15. The method of claim 10, wherein the period of REM sleep in the lateral position is less than 5 minutes, the method further comprising determining that the data is inconclusive.

16. The method of claim 9, wherein the dental appliance is a remote-control mandibular protruder, and the data is collected during an oral appliance titration study of the patient while the patient is sleeping with the remote-control mandibular protruder.

17. The method of claim 16, wherein the period of REM sleep in the supine position is greater than or equal to 5 minutes and a frequency of respiratory disturbances in the portion of the data from the period of REM sleep in the supine position is greater than a threshold frequency, the method further comprising:

identifying whether the data includes data collected for a predetermined titration range; and

in the event that the data includes data collected during the predetermined titration range, determining that the patient is not a favorable candidate for oral appliance therapy.

18. The method of claim 17, further comprising in the event that the data does not include data collected during the predetermined titration range, determining that the data is inconclusive.

19. The method of claim 17, wherein the predetermined titration range comprises a maximum protrusion of the remote-control mandibular protruder.

20. The method of claim 1, wherein the sleep data collection system is a polysomnogram device or a portable sleep monitor.

21. The method of claim 1, wherein the dental appliance is a remote-control mandibular protruder.

22. The method of claim 21, wherein the data is collected during an oral appliance titration study of the patient while the patient is sleeping with the remote-control mandibular protruder.

23. A non-transitory computer-readable recording medium for identifying a candidate for oral appliance therapy having computer-executable instructions stored thereon that, when executed by a computing device, cause the computing device to:

receive data from a patient associated with one or more periods of rapid eye movement (REM) sleep and non-REM sleep, wherein the data is received from a sleep data collection system, and wherein the data is collected from a patient, using the sleep data collection system, while the patient is sleeping with a dental appliance;

identify at least a portion of the data from a period of REM sleep;

identify a number of respiratory disturbances in the portion of the data from the period of REM sleep; and prospectively determine whether the patient is a favorable candidate for oral appliance therapy based on the number of respiratory disturbances in the portion of the data from the period of REM sleep,

wherein the determination of whether the patient is a favorable candidate for oral appliance therapy is made by evaluating the number of respiratory disturbances identified in data collected during REM sleep only;

wherein a favorable candidate for oral appliance therapy achieves a therapeutic end-point during oral appliance therapy; and

wherein the favorable candidate experiences less than a predetermined maximum number of respiratory disturbances during oral appliance therapy.

24. The non-transitory computer-readable recording medium of claim 23, wherein the sleep data collection system is a polysomnogram device or a portable sleep monitor.

25. The non-transitory computer-readable recording medium of claim 23, wherein the dental appliance is a remote-control mandibular protruder.

26. The non-transitory computer-readable recording medium of claim 25, wherein the data is collected during an oral appliance titration study of the patient while the patient is sleeping with the remote-control mandibular protruder.

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专利名称(译)	用于进行下颌突出物的远程滴定的方法和设备		
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[标]发明人	REMMERS JOHN TAM HUGO MACARTNEY TERRY SANTOSHAM PETER TOPOR ZBIGNIEW LUDWIK GROSSE JOSHUA		
发明人	REMMERS, JOHN TAM, HUGO MACARTNEY, TERRY SANTOSHAM, PETER TOPOR, ZBIGNIEW LUDWIK GROSSE, JOSHUA		
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摘要(译)

本文公开了用于在远程滴定下颌突出期间执行系统验证和提供预测标准的方法和装置。通过筛选阻塞性睡眠呼吸暂停受试者并且前瞻性地鉴定适合口腔矫治器疗法的受试者，可以改善口腔矫治器疗法的有效性。公开了用于在口腔矫治器疗法滴定系统上执行系统验证的方法和装置。此外，公开了用于在下颌突出物的远程滴定期间提供预测标准的方法和装置。此外，公开了用于远程滴定下颌突出物的显示结果的方法和装置。

